

***A GUIDE TO  
CALIFORNIA COMMUNITY  
PHARMACY LAW***

***EIGHTH EDITION  
2013-2015***

***By  
Fred G. Weissman, Pharm.D., J.D.***



***THE PERFECT SOURCE FOR:***

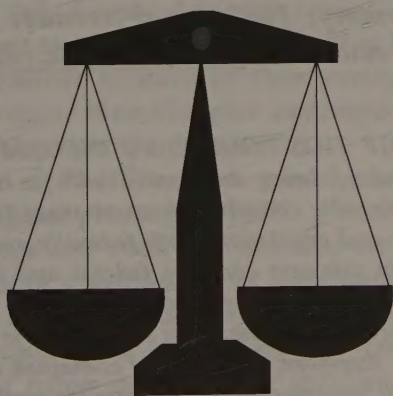
***The Pharmacy School Student  
The Board Exam Candidate  
The Practicing Community Pharmacist  
The Pharmacy Technician***



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***THE PURPOSE OF THIS BOOK IS TO INFORM AND NOT TO ADVISE. In case of being confronted with a legal issue it is important that the reader consult with an attorney familiar with the applicable statutes and regulations both federally and in California. The information in this text contains federal and California State statutes and regulations along with some case law. While this text book attempts to keep up to date, laws are subject to change or new laws are created – therefore, the material contained therein may not always be the latest information on a particular matter. The author and all other parties associated with the production of this text book hereby disclaim any and all liability or responsibility whatsoever for the representations, interpretations or reproductions of laws, regulations, and court case decisions referenced within.***

**ISBN 978-1-4243-3390-5**



## **DEDICATION AND ACKNOWLEDGEMENTS**

*First, I wish to recognize all the wonderful family members that are or have been a part of my life. While I lost my first wife, Terri, of almost 40 years to cancer in 2006 and who will always be in my thoughts, I was fortunate to find Marlene who I married in 2009. I have been blessed with four children in my first marriage (Kevin who is married to Laurel, Rachel who is married to Alan, Mark who is married to Melissa, and Michael who is married to Jamie), and two step sons (Michael and a Mark Berns). I have been further blessed with eight wonderful and loving grandchildren: Drew, Ashton, Ashar, Ryan, Tait, Autumn, Jordan, and Max.*

*I want to tell my children that they have been a source of encouragement because of their caring spirits, and how much I appreciate their thoughts and respectful comments as I undertook this project back in 1997.*

*This eighth (8<sup>th</sup>) edition comes almost sixteen years after the original printing in 1997. I wish to thank all those who have used this book and provided me with feed-back on how it has been a helpful aid in their study of pharmacy law, and how it can be further improved upon. As in the other editions, I must again express my very special thanks to my students and fellow colleagues at the University of Southern California School of Pharmacy who have made my teaching experiences both enjoyable and challenging.*

## ABOUT THE AUTHOR

*Fred G. Weissman is presently Associate Dean for Faculty/Student Affairs and Admissions, and Associate Professor of Pharmacy Practice at the University of Southern California School of Pharmacy. Among the several courses Dr. Weissman teaches is the Pharmacy Law Course. Dr. Weissman also teaches another law course entitled, "Medical Controversies And The Law" in another Department of the University. He has been recognized by his students as a Teacher of the Year on five separate occasions over the last eighteen years and was honored as the USC School of Pharmacy Alumnus of the Year in 2003. He has published numerous articles in a variety of pharmacy journals, and has traveled both nationally and internationally to lecture on a variety of pharmacy related subjects including issues dealing with both California and Federal Laws that impact the profession of pharmacy and health care in general. Dr. Weissman is a 1963 graduate from the U.S.C. School of Pharmacy and a 1989 graduate from Loyola Law School in Los Angeles.*

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# CHAPTER 1

## INTRODUCTION

The prospect of studying pharmacy law for the purpose of passing a pharmacy law course or the pharmacy state board examination does not come across to the average pharmacy student or pharmacist applicant as a very exciting undertaking. Even after going over the multitude of statutes and regulations that are specific to the practice of pharmacy in California, you may have come away from such instruction partly confused or perhaps forgetful of what you were suppose to learn.

As a pharmacy educator, I have been involved with the teaching of California Pharmacy Law Review Courses for over twenty years. I have learned that both pharmacy students and pharmacist-practitioners want a quick and easy way to learn the *applicable* and *practical* aspects of this body of law. They are saying, "Teach me the law that I need to know to practice retail pharmacy, as well as to pass a pharmacy law course exam or pharmacy board licensure examination - and make it simple to understand." With this directive in mind, this text has been compiled to help address the above stated issues and concerns.

Instead of simply going from statute to statute or from regulation to regulation to explain the law, each substantive legal point is raised in the form of a question or statement, then answered or addressed in a concise, understandable manner. Further, it is not uncommon for the State's *Pharmacy Law Text* to present similar or related laws in different portions of the *Text*. This book is organized in an attempt to bring the several similar statutes and regulations together for a more complete answer to a given question.

## 2 Introduction

The primary objective of this text is to address the practice issues concerning *California Pharmacy Law*. Therefore, you will not come across extensive discussions directed to what the remedies, consequences, or sanctions are if you violate a specific law.

There have been a number of additions and changes in the law since the last edition of this book primarily involving new requirements for new appointments of the pharmacists-in-charge to a pharmacy operation; new rule for pharmacists that do not have proof of fulfilling their C.E. requirements within the two-year relicensing period; a statement of the difference between an “inactive license” and a “retired license;” new requirements in information sought in the pharmacist relicensing process; new information pertaining to “Electronic Prescribing” and the requirements of “E-Prescribing;” new rulings regarding prescription label preparation; the rules governing the use of mobile pharmacies; new rules on general compounding of non-sterile products by a pharmacy; and continued rulings on internet prescribing as dictated by the Ryan-Haight Online Pharmacy Consumer Protection Act of 2008.

By way of format, this book contains eighteen chapters which cover the major items that a candidate filing for licensure with the California State Board of Pharmacy or the practicing pharmacist in California needs to know about the law as it applies to community pharmacy practice. Fourteen of the eighteen chapters are comprised of essential question- or statement- headings, which serve as topics that allow for concise discussions on the purpose and operation of a law or laws. The eighteenth chapter is exclusively devoted to a 170 multiple choice questions, and the *answers* to those questions.

*Chapter 2* does not specifically address either one’s practice of pharmacy or one’s state board examination study needs. However, the content of this chapter is important in understanding: 1) how the law is organized in the *California*



*Pharmacy Law Text*, 2) the difference between a *statute* and a *regulation*, 3) the *preemption doctrine* regarding federal versus state laws, and 4) the significance in the wording of a law based upon *mandatory* versus *permissive* language.

The next fifteen chapters (*Chapters 3 through 17*) attempt to organize the contents of your *California Pharmacy Law Text* under specific subject headings. *Chapter 18* is devoted to multiple choice practice questions, and is followed by a discussion of the answers to those questions.

Be aware that there are a number of laws that you as a practicing pharmacist in the State of California must know which are not contained in the *California Pharmacy Law Text* provided by the State. "Why?" you may ask. The major reason is that the *California Pharmacy Law Text* only covers those statutes and regulations that are laws put into effect by the State. Many of the federal laws that apply to pharmacy practice in California are not included in the *California Pharmacy Law Text* unless they were adopted as laws by the State legislature. Examples of such an adoption of laws are the majority of statutes from the federal *Controlled Substances Act* that has been incorporated in California's *Health and Safety Codes*. The fact that a federal law that applies to pharmacy practice is not in the *California Pharmacy Law Text* should not be construed as a body of law that is not needed to be known by the practicing pharmacist in this State. So take note of this very important rule, "**IGNORANCE OF THE LAW IS NO EXCUSE.**" You are obligated under the law as a licensed pharmacy practitioner to know all the law applicable to your profession and to practice that law accordingly.

Here, for example are some of the laws for which you as a pharmacy practitioner in the State of California are responsible, even though they are absent from the State's *California Pharmacy Law Text*, are: 1) the statute requiring a one-inch red "C" on the lower right corner of a prescription for a Schedule III, IV, or V controlled substance when integrated into your hardcopy nonscheduled drug

prescription files; 2) the provision, each time a prescription is dispensed, that a *Patient Medication Guide* for all drugs that the FDA has prepared such “*Guides*” for, has been provided to the patient to help them understand the risk versus benefits of the dispensed drug; 3) the requirements for placing prescription medications in child-resistant safety containers; 4) the purpose and processing of the federal *DEA Form 222* used for the ordering of Schedule II controlled substances; and 5) for every controlled substance dispensed to a patient, federal law requires that an auxiliary label be attached that states, “*This medication is not to be transferred or used by any other person other than the person it was prescribed for,*” or words to that effect.

Chapters 3 through 18 are summarized below.

*Chapter 3 (“PHARMACY’S CAST OF CHARACTERS”)* deals with such matters as the State Board of Pharmacy appointments and responsibilities, the role of the pharmacy inspectors, and the general duties and responsibilities of the pharmacist, pharmacy intern, and pharmacy technician. Also covered in this chapter are the prescription writing and furnishing rights of other members of the health care team such as the optometrist, naturopathic doctor, nurse practitioner, physician assistant, and the certified nurse midwife.

*Chapter 4 (“GENERAL PHARMACY PRACTICE CONCERNS AND PROFESSIONAL CONDUCT ISSUES”)* presents information pertaining to such issues as the circumstances when dangerous drugs or devices may be furnished without a prescription; who may transmit and who may receive an orally transmitted prescription order from a prescriber’s office; what it means to be designated as the “*pharmacist-in-charge*” or the “*designated representative-in-charge*”; rebates from pharmacies for referrals; preferential pricing arrangements; physician medication dispensing; the use of the Internet to transmit prescriptions; refusing to fill a prescription based upon one’s moral, religious, or

ethical beliefs; and the reporting to the Board of Pharmacy licensed employee thefts or impairments.

*Chapter 5 (“THE LAWS REGARDING PATIENT CONFIDENTIALITY AND QUALITY ASSURANCE”)* presents information on how the Health Insurance Portability And Accountability Act (HIPAA) will affect the practice of pharmacy in respect to a patient’s health care privacy and confidentiality rights. Further, this Chapter will discuss the major requirements for pharmacy under the State’s Quality Assurance – Medication Error Reporting Program, and what the Program intends to accomplish.

*Chapter 6 (“LAWS ENCOURAGING THE PHARMACIST TO PARTICIPATE IN PATIENT CARE SERVICES”)* discusses responsibilities that the pharmacist must either participate in or is encouraged to undertake to enhance patient care. While verbal consultation with the patient about their new prescription medications and maintaining patient medication profiles are mandatory patient care undertakings, engaging in such projects as cholesterol testing, providing emergency oral contraception, and administering immunizations, enables the pharmacist to promote him- or herself as a true health care professional.

*Chapter 7 (“DEALING WITH WRITTEN DOCUMENTATION IN PHARMACY PRACTICE”)* directs its attention to such matters as the information required on both a filled prescription and the label affixed to the dispensed drug container; the keeping of self-assessment surveys (involving general pharmacy practice, sterile compounding, and non-sterile compounding); information that must be recorded every time a prescription is refilled; the provision and retention of prescription transfer records; and the faxing or electronic transmission of prescriptions.

*Chapter 8 ("PATIENT ORAL AND WRITTEN COMMUNICATIONS")* focuses on such matters as the type of information required to be given to the patient during a drug consultation (both state and federal requirements); information to be furnished to the consumer regarding services provided by a pharmacy and the pharmacist; prescription price quotes; auxiliary label information; the provision of *Patient Medication Guides* where and when required; the purpose of "*Black Box Label*" warnings; and general requirements for advertising by a pharmacy.

*Chapter 9 ("THE BUSINESS OF PHARMACY AND THE DRUG WHOLESALER")* reviews issues involving consideration in the naming of a pharmacy; who may or may not own a community pharmacy in the State of California; space requirements for operating a pharmacy; pharmacy barrier and enclosure requirements; who may sign for prescription drugs when they arrive at the pharmacy from the wholesaler; the waiver requirement from the State Board of Pharmacy for off-site storage of pharmacy records; other matters related to pharmacy security; pharmacy permit requirements, and the special requirements for wholesalers and distributors of prescription drugs when such drugs are placed into the stream of commerce.

*Chapter 10 ("SPECIAL DRUG PRODUCTS AND DEVICES")* discusses such topics as the changes in the hypodermic needle/syringe laws regarding the sale of such items OTC; prescription drug and dosage form substitutions; dispensing of sample drugs by a pharmacy; the use of automated drug delivery systems; status of poisons sold in a pharmacy; the restrictions that exist regarding the sale of ephedrine-like products; and the redistribution of unused prescription drugs by pharmacies for indigent patients.



*Chapter 11 ("COMPOUNDING AND MANUFACTURING ISSUES IN PHARMACY PRACTICE")* outlines the new regulations established for sterile injectable compounded products and non-sterile compounded drug products prepared by a pharmacy, discusses issues that differentiate compounding from manufacturing practices in a pharmacy, and notes the requirements on compounding drug products for future furnishing and prescribers.

*Chapter 12 ("CLASSIFICATIONS OF SCHEDULED CONTROLLED SUBSTANCES")* arranges the different controlled substances according to their "Schedule" (II, III, IV, or V), and notes the common trade names for single-drug or mixture controlled substances.

*Chapter 13 ("SPECIAL CONCERNS IN DEALING WITH SCHEDULED II CONTROLLED SUBSTANCES")* discusses how special approved California security forms are to be used for the prescribing of controlled substances; the practice of E-prescribing; the role of the CURES Program and what it is suppose to accomplish; how omissions or mistakes on a prescription for Schedule II controlled substances are now handled; how emergency prescriptions and Schedule II orders for terminally ill patients are to be handled; how Schedule II prescriptions are handled when the patient is to receive less than what is ordered on the face of the prescription; and how a DEA Form 222 is used in the ordering of Schedule II drugs from a wholesaler or used in a transfer to another pharmacy or prescriber's office.

*Chapter 14 ("RULES CONCERNING SCHEDULE III, IV, AND V CONTROLLED SUBSTANCES")* reviews issues regarding controlled substances such as the filling of out-of-state Schedule III, IV, and V prescriptions; filing requirements for the Scheduled controlled substances; refill limits; auxiliary label information required; mailing concerns; inventory record keeping; disposal of unused

controlled substances; addict treatment programs; E-prescribing of controlled substances; and other related topics.

*Chapter 15 ("SIX NEW LAWS RECENTLY PASSED BY THE CALIFORNIA LEGISLATURE AND APPROVED BY THE GOVERNOR")* discusses new laws to be placed in effect in 2013. These laws involve" 1) extending the filling of refillable prescriptions up to 90 day supplies; 2) placing more controls on audits done at pharmacies by third party insurance payors; 3) expanding upon the CLIA waivers for pharmacists performing certain routine laboratory tests; 4) establishing hospital pharmacy centralized drug preparation and drug barcoding for hospitals within a 75 mile radius that are within the same ownership arrangement as the centralized hospital pharmacy; 5) restricting pharmacists involved in a civil suit with a patient from influencing the plaintiff patient to not file a complaint with the Board of Pharmacy; and 6) the allowing of registered nurses in licensed clinics to dispense drugs to patients.

*Chapter 16 ("IMPORTANT TIME PERIODS ALLOTTED BY CALIFORNIA PHARMACY LAW")* is organized such that a question on a specific issue pertaining to a time period is answered with the appropriate allotted time period. Among some of the areas addressed in this chapter are notification of the State's Pharmacy Board of a change in the licensee's address; notification to the Board when a change in ownership or filing for bankruptcy has occurred; the period of time for which specific prescription records must be kept; and what expiration dates may be used on dispensed medications, along with many more time period requirements.

*Chapter 17 ("BEING PREPARED FOR A STATE BOARD OF PHARMACY INSPECTION")* suggests 38 items that might be probed during a visit from a Board of Pharmacy inspector.

**Chapter 18 ("MULTIPLE CHOICE REVIEW QUESTIONS").** This chapter is exclusively devoted to 170 multiple choice test questions with each question explained in a detailed manner. The 170-question test is designed to aid the reader in reviewing the subject matter presented in Chapters 2 through 17. It also serves as a practice exercise to strengthen your examination skills in *California Pharmacy Law*, especially if you plan to sit for the California State Board of Pharmacy Examination. Concerning the latter point, this chapter will also help you develop the confidence and test approach you need in order to do well on the jurisprudence portion of the Board examination. This Chapter is followed by not only the correct answer to each of the multiple choice questions, but an explanation for each of the answers in order to give you an understanding of why the choice for each question is correct or the most correct answer.

In this book you will find that whenever a principle of pharmacy law is discussed, the code number of the corresponding statute or regulation will be cited. In order to be fully effective, this text should be used in conjunction with the most recent edition of the *California Pharmacy Law Text*. When a code number is cited, you may want to refer to that specific law in the *California Pharmacy Law Text* to read the law exactly as it is written. Using the two texts together in this way will reinforce your understanding of each given law.

The objective of this *Guide* is to clarify your understanding of California's pharmacy laws. If you read it carefully while continually cross-referencing with the State text, you will be surprised at how simple the principle of this body of law really is. Furthermore, it is the author's hope that the material presented in this text will not only address all of your California pharmacy law questions, but will be enjoyable reading at the same time – if that's at all possible.





## CHAPTER 2

### ***CALIFORNIA PHARMACY LAW BACKGROUND INFORMATION***

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## **HOW IS THE CALIFORNIA PHARMACY LAWBOOK ARRANGED?**

The *California Pharmacy Law Text* (the text prepared through the efforts of the California State Board of Pharmacy) is now composed of four major sections: 1) *The California Business and Professions Codes*, 2) *The California Code of Regulations* from the Administrative Codes, 3) *The California Health and Safety Codes* (which specifically involves the Uniform Controlled Substances Act), and 4) *The California Civil Codes*. These particular code books are generally comprised of numerous volumes covering several thousand pages. Only excerpts derived from these code volumes that directly pertain to pharmacy practice issues are placed in the State's *California Pharmacy Law Text*.

Most of the codes extracted from the *California Business and Professions Codes* are found between Sections 4000 and 4426. *The California Business and Professions Codes* pertaining to pharmacy practice matters underwent reorganization in 1996-97 in order to improve clarification, to place similar subject matter codes together, and to renumber all the codes within this section. All references to the *California Business and Professions Codes* in this textbook use the new set of Code numbers. There are other important codes within the *Business and Professions Codes* that apply not only to California licensed pharmacists, but apply to other professions as well and are dispersed throughout the *Business and Profession Codes*. Some examples of these applicable codes are the laws pertaining to the providing of rebates or discounts (*CA B & P Code*, §650), professional advertising requirements (*CA B & P Code*, §651), and the reporting of pharmacy-related settlements or arbitration awards (*CA B & P Code*, §802).

Pertinent pharmacy practice codes found in *Chapter 17, Title 16 of the California Code of Regulations* span from

about *Section 1700* to *Section 1793.8*. These regulations generally give more meaning and depth to issues of pharmacy practice than do many of the codes found in the *California Business and Profession Codes*.

The third group of codes, starting at *Section 11053* and ending at about *Section 11256* of the *California Health and Safety Codes* deal exclusively with the control and distribution of scheduled drugs or controlled substances. Many of these codes are derived directly from the federal codes contained in the *Controlled Substances Act* (See *Code of Federal Regulations [CFR]* under *Title 21, Chapter 11* starting from *Section 1301*).

A fourth set of codes have been added to the *California Pharmacy Law Text*, specifically the State codes addressing confidentiality of medical record information. Codes pertaining to the rules for disclosure of medical information are found in the *California Civil Codes, Sections 56 to 56.37*.

### ***IS THERE A DIFFERENCE BETWEEN A STATUTE AND A REGULATION?***

The codes found in the *California Business and Professions Codes*, the *California Health and Safety Codes*, and the *California Civil Codes* are *statutes*. The codes that make up the *California Code of Regulations* are classed as *regulations*. The difference between a statute and a regulation is simply based upon the governing body that passes the law. If the law is created by the state legislature, meaning that it is passed by both the State Senate and the State Assembly and approved by the Governor, then the law is referred to as a *statute*. The state legislature and the Governor are empowered through the state constitution to create state agencies to develop and enact *regulations*. The California State Board of Pharmacy is an example of an

## **14 Background Information**

agency authorized to enact regulations pertaining to the practice of pharmacy in the State.

*“The Board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public...” (Calif. Bus. & Prof. Code, Sec. 4005)*

Part of the State Board of Pharmacy's role is to ensure that the applicable statutes created by the state legislature and the regulations promulgated by the Board of Pharmacy are enforced. Because of the limited functions of the State Board of Pharmacy as compared to the state legislature, this departmental agency is able to enact regulations that specifically concern the practice aspects of the pharmacy profession in California. Regulations carry about the same weight as statutes in regard to their control over the practice of pharmacy in the state. However, if a regulation conflicts with a statute on a specific issue, the matter is generally deferred to the Office of Administrative Law for resolution, and if necessary to the Governor.

Many of the State statutes are referred to as “*enabling statutes*” where the State legislature directs the Board of Pharmacy to act in the creating of a law for the sake of public safety.

### **THE WEIGHT OF A FEDERAL STATUTE VERSUS A STATE STATUTE OR REGULATION AND THE PREEMPTION DOCTRINE**

The “*Preemption Doctrine*” applies when there is a conflict between a federal and state statute. Under the doctrine, the federal statute will generally always outweigh the state statute or regulation. There are, however, instances where a state law may not completely coincide with a federal law. With regard to pharmacy laws, we occasionally run across this problem in the area of drug schedules for



controlled substances. As an example, under the federal controlled substances laws, the drug *Paregoric* (*Camphorated Tincture of Opium*) is classified as a Schedule III drug. In California this same drug substance is classified as a Schedule II controlled substance if it is dispensed as pure *Paregoric*. This would appear to be a conflict between a federal and a state law. However, the state law may be more stringent than the federal law if the state has a justifiable basis for enacting the tougher law. Here, the state would argue that the state is within the limits of the U.S. Constitution in the enactment of a stricter law than the federal law, if such a law's purpose is to promote the health and welfare of the state's citizens. In other words, the state would contend that having the drug, pure *Paregoric*, under the state's Schedule II controlled substances classification, reduces the potential for the drug's abuse.

While a state can make a law more stringent than a federal law (as long as there is not a conflict with the U.S. Constitution), the state cannot make a law less stringent than a federal law. Controversy presently exists between California's law on the medical use of marihuana, and the federal laws making marihuana illegal. This conflict of law is pending further review with California allowing licensed physicians to prescribe this substance for specific and legitimate medical purposes.

### *MANDATORY VERSUS PERMISSIVE LANGUAGE OF A LAW*

In reading a statute or regulation, you will find that each is stated in very specific language to which you will need to pay careful attention. A law is *mandatory* if it contains such terms as "*must*" or "*shall*." A mandatory law must be followed precisely as stated. The following is an example of such a law:

*“No person shall furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.”* Calif. Bus. & Prof. Codes, Sec. 4059[a].

The above allows for no deviation from what is stated. A law containing *permissive* language will give the pharmacist discretion on how to proceed. Permissive language uses the terms “*may*” or “*can*” to allow for case-by-case judgment on the part of the pharmacist. Laws that contain permissive language are generally less prevalent than laws that contain mandatory language. An example of a law containing permissive language would be worded in the following manner:

*“A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist’s responsibilities under the Pharmacy Law.”* Title 16, Calif. Code of Reg., Sec. 1709.1(f)

### ***DOES CALIFORNIA PHARMACY LAW ENCOMPASS ALL PHARMACY PRACTICE SITUATIONS?***

Generally speaking, regulations are usually more encompassing of what is required or expected in a specific practice circumstance than are statutes. However, the regulations may not address every practice situation that arises. For example, the *California Pharmacist Consultation Regulations* are somewhat limited as to what is expected of the pharmacist (see *Title 16, Calif. Code of Regs. Sec. 1707.2*). Even though the *Consultation Regulations* state that the pharmacist must consult the patient orally on each new prescription that is provided, there is no guidance in the law

book on what to do if the patient does not speak English (however, newer laws are addressing this issue by requiring pharmacists to offer interpretative services). When a new situation develops which is not directly addressed by existing laws, any one of the following things can happen: 1) the state legislature addresses the issue by passing a statute; 2) the state Board of Pharmacy passes a regulation to address the issue; 3) the matter is decided in a court of law; or 4) the state attorney general's office will render an opinion to serve as a guide on the matter.

In the forthcoming pages, I try to expand upon what might otherwise appear to be general laws or rules, and to provide the State's Attorney General's opinions or court decisions where appropriate. Usually, when the Attorney General reviews an issue regarding a particular statute or regulation, he or she will attempt to determine what is reasonable and not in conflict with either the U.S. Constitution or federal laws.

### *ARE THE ATTORNEY GENERAL OPINIONS LAW?*

When the Attorney General's Office renders an opinion on a pharmacy related matter; it serves as guidance rather than a law. As an example, in one such Attorney General opinion, there is an attempt to limit nonscheduled drug prescriptions that have a "refill prn" designation from being refilled over a period of one year without contacting the prescriber. Thus, if you refill the prescription having a "refill prn" designation after a year without contacting the prescriber you really haven't broken a law and therefore you may not be subjected to any criminal sanctions. However, by refilling the prescription after a year, you have acted outside the standard of practice the opinion has attempted to create. Accordingly, if something should happen to the patient as a result of your intentional or unintentional action to defy the opinion, the patient could argue it under a legal claim that

you were not following a standard of practice in calling her physician for further refill approval after the year and therefore could be found civilly liable.

### ***WHAT ARE THE COMMON LEGAL ACTIONS THAT CAN BE BROUGHT AGAINST A PHARMACIST?***

There are three common types of legal actions that can be brought against a licensed pharmacist for a matter of wrongdoing: 1) A Civil Action, 2) A Criminal Action, and/or 3) An Administrative Action. These actions can be brought separately or collectively.

A *civil action* is generally instituted by an individual who has been harmed or injured by the actions of the pharmacist. An example of a civil lawsuit against a pharmacist is where a patient has been injured or harmed as a result of the dispensing of the wrong drug and the patient experiences a harmful effect. Civil suits are usually between individuals, whereby the party bringing the suit generally wants to be compensated with money for the injury caused.

A *criminal action* occurs when a law is broken, and a government entity (federal, state, county, or city government brings the action). So, if a pharmacist gives out a prescription medication without a prescription, that pharmacist has broken the law, and based upon the severity of the nature of the law broken can face both a fine and prison time. Generally the laws that are broken fall within the infraction, misdemeanor, or felony classifications. The more common laws that pharmacists break are within the misdemeanor category. Generally felonies are associated with violations of the Uniform Controlled Substance Act.

An *administration action* involves the State Board of Pharmacy taking action against a pharmacist's license if the licensee breaks the law or possibly where the board adjudges the pharmacist to be in violation of specific professional conduct standards. The Board of Pharmacy may then act by revoking, suspending, placing the holder's license on probationary status, or providing a letter of admonishment.



## CHAPTER 3

### PHARMACY'S CAST OF CHARACTERS

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## **THE CALIFORNIA STATE BOARD OF PHARMACY APPOINTMENTS AND RESPONSIBILITIES**

The California State Board of Pharmacy is under the jurisdiction of the Department of Consumer Affairs. The Board consists of thirteen (13) members, eleven (11) of whom are appointed by the Governor. The remaining two members are appointed by a committee of the state Senate and by the Speaker of the Assembly.<sup>1</sup> The two remaining members shall not be licensed pharmacists.<sup>2</sup> Seven of the Governor's appointments must be registered pharmacists, five of whom must be actively practicing pharmacists in at least one of the following practice settings: a) an acute care hospital, b) an independent community pharmacy (pharmacist cannot own more than four pharmacies by definition), c) a chain community pharmacy (the chain must exist of at least 75 or more pharmacies under the same ownership in California), d) a long-term health care or skilled nursing facility, and e) a pharmacist who is a member of a labor union that represents pharmacists.<sup>3</sup> The other six must be non-pharmacist members.<sup>4</sup> The term for each Board member is four years and each Board member may only serve two terms.<sup>5</sup> A quorum for a Board meeting requires at least seven members.<sup>6</sup> Meetings are held at least once every four months.<sup>7</sup>

The major responsibility of the Board is the adoption of rules and regulations pertaining to the practice of pharmacy as are necessary for the protection of the public.<sup>8</sup> The Board is also responsible for preparing and conducting licensing examinations, investigating violations of laws under its jurisdiction, and taking disciplinary action against licensees who violate those laws.

## **WHAT IS THE ROLE OF THE PHARMACY INSPECTORS?**

A pharmacy board inspector's role is to inspect, during business hours, all pharmacies, medical device retailers, veterinary drug retail operations, dispensaries,

wholesalers of drugs or medical devices and operations in which drugs or devices are compounded, stored, dispensed or sold..<sup>9</sup> Board inspectors may also inspect physician offices or clinics where drugs are ordered, stored and dispensed to ensure they are operating under a license issued by the Board of Pharmacy.<sup>10</sup>

At one time all board inspectors were required to be registered pharmacists. Presently the registered pharmacist requirement is no longer the case.

A board inspector, having "reasonable cause," has the power to arrest, without a warrant, any person believed to have violated state pharmacy laws, usually constituting a felony or a misdemeanor.<sup>11</sup>

When visited by an inspector, the pharmacy owner or manager must furnish upon request the names of the pharmacy owner(s), manager(s), and employees with a brief statement of the capacity in which these persons are employed.<sup>12</sup> An inspector is allowed to remove from a pharmacy's files and records any prescriptions that are the subject of the investigation. In so doing, the inspector must provide a signed receipt to the pharmacy specifically stating the prescription documents or drugs which were removed. Any released prescription documents should be photocopied and the copies retained in the pharmacy along with the receipt.<sup>13</sup>

### *THE EXECUTIVE OFFICER OF THE BOARD*

The Board of Pharmacy has the authority to appoint an executive officer. This executive officer is a full-time paid employee of the board. The role of the executive officer is to exercise the powers and perform the duties delegated by the board.<sup>14</sup>

The executive officer is in a position to influence policy changes and has the authority to institute accusation proceedings against licensed pharmacists who have broken the law.<sup>15</sup> Of particular interest is that the executive officer of the Board does *not* have to be a licensed pharmacist.



## **WHO MAY PRESCRIBE OR FURNISH DRUGS?**

### **Physicians, Dentists, Podiatrists, & Veterinarians**

The law states, "A person may not furnish any dangerous drug or dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.<sup>16</sup> Also included in the category of "physician" is a Doctor of Osteopathic Medicine (D.O.).<sup>17</sup>

There is generally very little exception to the above rule of law. However, under a well-structured protocol, usually devised by a prescriber or a committee of prescribers, certain other personnel such as nurse practitioners, physician assistants, certified nurse midwives, naturopathic doctors, and even pharmacists can furnish drugs under specific conditions.<sup>18</sup> The so-called "extended scope of practice legislation" now gives pharmacists the opportunity to initiate and adjust drug therapy pursuant to a prescriber supported protocol in a community pharmacy setting.<sup>19</sup> Prior to 2000 pharmacists could only adjust drug therapy using protocols developed by and for licensed health care facilities such as hospitals, skilled nursing facilities and clinics. If a pharmacist is to have the authority to make such drug initiations and adjustments or furnish specific drugs under a protocol, the individual authorized must follow the terms of the protocol to the letter. The prescribers granting this authorization could assume the major responsibility and possible liabilities associated with the administration of the protocol.

What happens to a prescriber's prescribing privileges if that prescriber should retire or become deceased? A physician who retires and retires his or her license cannot prescribe drugs. However, if the retired prescriber is issued a "voluntary service" license and provides voluntary, unpaid service that retired prescriber will still be allowed to practice medicine and write prescriptions.<sup>20</sup>

Regarding the refilling of prescriptions issued by a prescriber who has recently died has taken on varied rules

by different states. North Carolina provides that a pharmacist under specific circumstances can refill prescriptions for up to a 90 day supply.<sup>21</sup> Pennsylvania law takes the opposite position, "No prescription may be knowingly filled or refilled for a patient whose prescription was written by a prescriber who is deceased or no longer in practice."<sup>22</sup> California does not appear to have a ruling on this point and would seem to take a "reasonableness" position on this matter. Obviously the Board is concerned with what is in the best interest of the patient's health. In most cases a pharmacist may not get word of the death of a prescriber until some time henceforth since it is not expected of that pharmacist to call the prescriber's office every time a prescription is to be refilled to see if the prescriber is still "above the sod." Therefore, it would seem reasonable to refill a prescription that has refills even though the pharmacist may not know the prescriber is now deceased. Once the pharmacist has knowledge that the prescriber is deceased, and the patient wants refills, the judgment of the pharmacist in providing either a whole amount or partial amount of a refillable prescription would seem reasonable based upon the medical condition of the patient and with advisement to the patient that they need to be followed up by a new prescriber, and that you as the pharmacist would be happy to provide that new prescriber with the patient's past medication history upon the new prescriber's request and the patient's approval.

### Optometrists

Optometrists have *limited* authority to prescribe certain drugs. The Board Of Optometry has certified qualified optometrists to use and prescribe therapeutic pharmaceutical agents (TPAs) in their practice. TPA-certified optometrists will have a letter "T" at the end of their license number (e.g. OPT 12345-T). The "TPA" designation appear at the right of the prescriber's license number on the prescription. Verification for prescription writing authority may be validated by going online at

[www.optometry.ca.gov](http://www.optometry.ca.gov). Those optometrists that are TPA-certified may prescribe a variety of drugs in the management of a number of eye disorders common to the optometrist's practice such as:<sup>23</sup>

- Topical anti-allergy and topical anti-inflammatory drug agents including topical and systemic steroids (the optometrist will need to consult with an ophthalmologist if the patient's condition worsens 72 hours after diagnosis, if inflammation still persists after three weeks, if the patient still needs to take the medication six weeks after the diagnosis, or if the patient's condition reoccurs within three months);
- Optometrists who receive special training in pharmacology and glaucoma management, with the provision of certification, can now prescribe for oral as well as topical agents in the treatment of glaucoma in patients over 18 years of age. This ruling was instituted in 2008. Prior to 2008 certified optometrists could only use topical antiglaucoma agents in the treatment of open-angle glaucoma only and were instructed not to use more than two concurrent topical medications in treating the patient for primary open angle glaucoma in patients over the age of 18;<sup>24</sup>
- Oral antihistamines for the treatment of ocular allergies;
- Other oral antibiotics or anti-infectants in addition to tetracycline (as a general rule if the patient's infection condition worsens 72 hours after diagnosis or if the condition does not resolve within 10 days after diagnosis and treatment, the patient shall be referred to an ophthalmologist):
  - Dicloxacillin
  - Amoxicillin (also with the clavulanate salt)
  - Erythromycin
  - Clarithromycin
  - Cephalexin
  - Cephadroxil
  - Cefaclor
  - Trimethoprim with sulfamethoxazole

- Ciprofloxacin
- Azithromycin – use shall be limited to the treatment of eyelid infections and chlamydial disease manifesting in the eyes.
- Topical antiviral medication (limited to 3 weeks)
- Oral acyclovir (limited to 10 days)
- Codeine formulated with a nonscheduled analgesic drug or hydrocodone formulated with a nonscheduled analgesic drug. The use of these agents shall be limited to 3 days with a referral to an ophthalmologist if the pain persists. (The optometrist must be registered with the DEA in order to prescribe any Scheduled controlled substance.)

Regarding the prescribing of these drugs for patients one year or younger, which appeared in an earlier version of the Calif. Bus. & Prof. Codes for Optometrists, appears to have been removed from the specific code section.<sup>25</sup>

### *Naturopathic Doctors (NDs)*

The Naturopathic Doctor (ND) may work with a licensed physician under a protocol to furnish or order non-scheduled or Schedule III, IV, or V controlled substances for patients on the protocol and within the scope of practice the physician or physicians are practicing and have authorized the ND to furnish specific prescription drugs as outlined in the prescriber directed protocol. It will be required that the ND work under a formulary developed by the physician or group of physicians authorizing the protocol that the ND must follow.<sup>26</sup> A physician may only supervise up to four NDs at one time.<sup>27</sup>

In order for an ND to furnish or order prescription drugs, the ND must have a furnishing number preceded by the letters “NDF” that is provided by the Bureau of Naturopathic Medicine. An example of how the NDF number would be displayed on the prescription is “NDF-704.”<sup>28</sup>



Section 3640.7 of the Calif. Business & Professions Codes allows an ND to independently prescribe epinephrine to treat anaphylaxis and further prescribe natural or synthetic hormones without being bound to a physician-directed protocol. As an example, the ND may furnish Armour's Thyroid (as a natural hormone) without authorization of a physician-directed protocol. Products such as testosterone (a Schedule III controlled substance), while considered a natural product may only be authorized by the physician-directed protocol since the governing California statute states that all controlled substances, including Schedule IIIs, must be ordered in accordance with a patient-specific protocol approved by the treating or supervising physician.<sup>29</sup> In order to furnish any controlled substances, the ND must be registered with the DEA. If there is any question about whether or not a prescription drug can be ordered by the ND, the pharmacist has the right to request a copy of the physician-directed protocol from the authorizing physician.

#### *Physician Assistants (PAs)*

A registered Physician Assistant (PA) under the supervision of a licensed physician and pursuant to a written protocol may do the following:<sup>30</sup>

- Administer or provide medications to a patient.
- Transmit orally, or in writing on a patient's record or in a transmittal order, a prescription from his or her supervising physician to a registered pharmacist for filling.
- Furnish prescriptions for Schedule II through V controlled substances pursuant to a prescriber's directed written protocol. Such prescriptions must be written for on a state approved prescription security form provided to the PA.

It is important to note that under California law PAs are not allowed to prescribe medications - they may only furnish medications pursuant to a prescriber developed protocol.

Regarding prescriptions for Schedule II to V controlled substances, the PA if registered with the DEA may also furnish drugs within these scheduled categories as long as authorized within the prescriber's written protocol. Only the PA's signature is required on the prescription. However, any written drug order issued by a PA to a patient shall contain the printed name, address, and phone number of the supervising prescriber, the printed or stamped name and license number of the PA, and the signature of the PA.<sup>31</sup> (Not only PAs, but now nurse practitioners [NPs] and certified nurse practitioners [CNP]s all have the authority to write for Schedule II through V controlled substances as long as they are registered with the DEA and write for a controlled substance contained in the prescriber's authorized protocol.<sup>32</sup>) As of January 1, 2005 all prescriptions written for any scheduled control substances must now be written on a special California approved security prescription form.<sup>33</sup> State *Triplicate* prescriptions are no longer valid as of January 1, 2005 for Schedule II controlled substances.

In order for a pharmacist to be secure in his or her belief that a PA's written or oral order for a prescription drug is authentic or allowable, the pharmacist should consider doing the following:

- Require that a physician-supervisor signed copy of the PA protocol statement be provided. This should definitely be requested if the pharmacy will have an ongoing relationship with that PA's practice. In the state nursing laws, that have application to PAs, it specifically states the following:

*"A copy of the standardized procedure or protocol relating to the furnishing or ordering of controlled substances by a CNM or NP shall be provided upon request to any licensed pharmacist who is uncertain of the authority of the CNM or NP to perform these functions."*<sup>34</sup>

- Require that the PA provide their registration number issued by the PA licensing board and proof of having a DEA Registration number.
- On a written or oral prescription transmission, if any doubt exists on the part of the receiving pharmacist, that pharmacist should contact the PA's practice and speak to the supervising-physician to determine the authenticity of the prescription (in compliance with the written protocol) and document the manner in which approval was obtained.

When a prescription is written by a PA (also applies to prescriptions written by nurse practitioners and certified nurse midwives) according to a prescriber authorized protocol; upon filling the prescription by the pharmacist, the name of either the prescriber or the PA (or nurse practitioner or nurse midwife or naturopathic doctor) must be placed on the label affixed to the prescription.<sup>35</sup> It is not required to have both names.

A PA, pursuant to a prescriber authorized protocol stipulating the prescription drugs that are allowed and any procedures, may hand to a patient of the supervising physician a properly labeled prescription drug prepackaged by a physician, a manufacturer, or a pharmacist.<sup>36</sup> A PA may also sign for both the request and receipt of sample prescription drugs or medical devices that are described in a prescriber authorized protocol.<sup>37</sup> These same PA allowances also apply to a nurse practitioner and a certified nurse practitioner as long as the prescriber protocol authorizes these activities.

### *Nurse Practitioners (NPs)*

The rules that apply to licensed PAs for the most part apply to Nurse Practitioners (NPs).<sup>38</sup> The codes allow the NP to furnish drugs and devices in clinics and general acute care hospitals. Under a standard protocol developed by licensed physicians associated with a clinic or hospital, or private practice, licensed NPs registered with the DEA may furnish

Schedule II through V controlled substance prescriptions, as well as nonscheduled drug prescriptions. NPs, like PAs who are registered with the DEA, may now order their own security prescription blanks and furnish Schedule II, III, IV and V controlled substances pursuant to a prescriber written protocol authorizing the NP to do so. As with PAs, any written drug order issued by an NP to a patient shall contain the printed name, address, and phone number of the supervising prescriber, the printed or stamped name and license number of the NP, and the signature of the NP.

Only California licensed NPs employed by or having a contractual relationship with a supervising-physician, medical group, or health care facility; or employed by a public entity or nonprofit clinic in California may furnish prescriptions under a physician-supervised protocol.<sup>39</sup>

Whenever there is any doubt on the part of the pharmacist regarding the filling of an NP generated prescription, the pharmacist should also follow the procedure for authenticating the information using the same standards set forth above under the "Physician Assistant" subject heading.

### *Certified Nurse Midwives (CNMs)*

Certified Nurse Midwives (CNMs), pursuant to a standardized protocol, may also issue, write, or transmit orders from a supervising physician to furnish patient-specific drugs and/or devices in certain settings.<sup>40</sup> Also note the following related to CNM practices:

- CNMs are now authorized to furnish and order controlled substances provided that they have a DEA registration number and the furnishing of the controlled substance is pursuant to a physician-supervised protocol.<sup>41</sup> Besides the furnishing of Schedule III, IV, or V controlled substances, the CNM may also furnish Schedule II controlled substances.<sup>42</sup> As of January 1, 2005 all prescriptions written for any scheduled



controlled substance must be written on a special State of California approved security prescription form.<sup>43</sup>

- CNMs may not furnish prescription drugs or devices from their own practice (where the CNM is the sole owner of the practice).
- CNMs must obtain a “furnishing number” from the Board of Registered Nurses in order to furnish prescription drugs via a protocol approved and supervised by a licensed physician or physicians. This number shall be included on all transmittals of orders for drugs or devices by the CNM.<sup>44</sup>
- A CNM may only furnish those drugs on the protocol that are within the scope of the CNM’s practice such as for family planning services, perinatal services, or for routine health care to essentially healthy persons.<sup>45</sup>
- A CNM, pursuant to a prescriber’s protocol, may furnish antibiotics to the sexual partner(s) of a patient with a diagnosed sexually transmitted chlamydia, gonorrhea, or other sexually transmitted infection without examination of the patient’s sexual partner.<sup>46</sup> It is important to note that if the CNM places on a prescription the name of one of the patients and refers to the consort as partner (e.g. *Jane Smith & Partner*) the name of the partner does not have to be determined, and the information on the prescription label can simply say, *Jane Smith & Partner*.<sup>47</sup> This is an exception to the general prescription rule under the California Bus. & Prof. Code, Sec. 4040[a][1][A] that states, “The prescription shall include the following: (A) The name or names... of the patient or patients.” The above rule also applies to physicians, PAs and NPs.

### ***SUMMARY OF PA, NP, CNM, AND ND FUNCTIONS RELATED TO PRESCRIPTION DRUG FURNISHING***

The following is a summary of prescription drug furnishing rules that were discussed above when such furnishing involves a PA, NP, CNM or ND (also applies to pharmacists):

- PAs, NPs, CNMs and NDs may write for all prescription drugs allowed for on a prescriber authorized written protocol. This includes Schedule II, III, IV, and V controlled substances as long as they are approved pursuant to the prescriber supervised protocol and the PA, NP, and CNM are registered to furnish such drugs with the DEA. The ND is limited to Schedule III, IV, and V drugs.
- A physician shall not supervise more than four physician assistants or four nurse practitioners, or any combination of the four, at one time.<sup>48</sup>
- CNMs may only write for prescription drugs that are within the physician authorized protocol and are related to family planning services, prenatal or perinatal care, and child birth delivery services.<sup>49</sup>
- PAs, NPs CNMs or NDs who are authorized to write for Schedule II, III, IV, or V controlled substances must do so using a California approved security prescription form issued specifically to the PA, NP, CNM or ND.
- Any written drug order issued by a PA, NP, CNM or ND to a patient shall contain the printed name, address, and phone number of the supervising prescriber, the printed or stamped name and license number of the PA, NP, CNM or ND and the signature of the PA, NP, CNM or ND.
- A prescription label affixed to a prescription drug vial as the result of the order by a PA, NP, CNM or ND must contain either the name of the supervising prescriber or the name of the PA, NP, CNM or ND.<sup>50</sup>
- A PA, NP, or CNM, pursuant to a physician authorized protocol, may write a prescription for an antibiotic to treat a sexually transmitted Chlamydia or other sexually transmitted infections for the examined patient as well as for the patient's partner (who does not need to be examined).<sup>51</sup> Furthermore, the pharmacist filling such a

prescription only needs to place on the prescription label the full name of the examined patient and the word “partner” as identification for the second party who is to also receive the antibiotic.

- A PA, NP, CNM, or ND may sign for both the request and receipt of sample prescription drugs or medical devices from a manufacturer or supplier as long as those samples are allowed in accordance with a prescriber authorized protocol.<sup>52</sup>

### ***WHAT DUTIES ARE GENERALLY EXPECTED OF A REGISTERED PHARMACIST?***

The duties generally expected of a registered pharmacist, other than the purchasing, compounding, and filling of prescription drugs for patients, include the following:<sup>53</sup>

- Receive a new prescription order orally from a prescriber or other person authorized by law.
- Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.
- Identify, evaluate and interpret a prescription.
- Interpret the clinical data in a patient medication record system or patient chart.
- Consult with any prescriber, nurse or other health care professional.
- Supervise the packaging of drugs and check the packaging procedure and product upon completion.
- Be responsible for all activities of pharmacy technicians to ensure that such activities are performed completely, safely and without risk of harm to patients.
- Perform any other duty which federal or state law or regulations authorizes only a registered pharmacist to perform.

- Perform all functions which require professional judgment.

While the above provides a general base of responsibilities assigned to the pharmacist, there are some other specific activities in which the pharmacist can engage in under an expanding “scope of practice” allowance. Examples of this expanded scope of practice areas are the following:

- Administering, orally or topically, drugs and biologicals pursuant to a prescriber’s order.<sup>54</sup>
- Performing skin punctures for purposes of training patients to withdraw their blood in order to perform self-assessment tests to monitor medical conditions including, but not limited to diabetes.<sup>55</sup> This ruling has been extended to allow pharmacists to perform blood tests for other purposes as well, such as to determine if one’s blood cholesterol level is too high.<sup>56</sup> However, such testing appears to be dependent upon training and the type of site where this procedure is performed.
- After receiving proper training, a pharmacist may take a person’s blood pressure. After the blood pressure reading, the pharmacist may: a) inform the person of the result; b) render an opinion as to whether the reading is within a high, low or normal range; and c) advise the person to consult with a physician.<sup>57</sup> The pharmacist performing this service is required to “utilize commonly accepted community standards in rendering opinions and referring patients to physicians.”<sup>58</sup>
- Also after receiving training, a pharmacist may be certified to provide a patient with an emergency oral contraceptive pursuant to a government sponsored protocol and immunization injections pursuant to a physician authorized protocol (see Chapter 6 for details on the pharmacist’s responsibilities in these two areas).<sup>59</sup>
- Performing the following procedures or functions as part of the care provided by a licensed health care facility, licensed clinic, community pharmacy, or a health care service plan developed by health care professionals in



accordance with written policies, procedures, or protocols developed by a committee of health care professionals which includes physicians, pharmacists, and nurses, with the approval of the facility administrator:<sup>60</sup>

- Ordering or performing routine drug therapy related patient assessment procedures, including temperature, pulse, and respiration.
- Ordering drug therapy related laboratory tests.
- Administering drugs and biologicals by injection pursuant to a prescriber's order.
- Initiating and adjusting the drug regimen of a patient according to written protocol standards.<sup>61</sup>

### ***THE PHARMACIST-IN-CHARGE (PIC) OBLIGATIONS AND RESPONSIBILITIES***

Any party that operates a pharmacy must have a designated pharmacist-in-charge. The permit, and all renewals for a permit to operate a pharmacy, must report the name of the pharmacist-in-charge (as well as the names of all owners; the names of officers if the operation is in the form of a corporation, and the form of business ownership).<sup>62</sup> If there is any change in the pharmacist-in-charge, as well as a change in the owners, or corporate officers, the Board of Pharmacy must be notified in writing within 30 days of that change.<sup>63</sup>

No pharmacist shall be the pharmacist-in-charge of more than **two** pharmacy operations at any one given time.<sup>64</sup> If a pharmacist should serve as pharmacist-in-charge of two pharmacies, the two pharmacies shall not be separated by a driving distance of **more than 50 miles**.<sup>65</sup> Furthermore, a pharmacist cannot serve concurrently as a pharmacist-in-charge if he or she also serves as a "representative-in-charge" (previously referred to as an "exemptee-in-charge") for a wholesaler, or a veterinary food-animal drug retailer.<sup>66</sup>

A pharmacist may refuse by a written statement to the owner to act as a pharmacist-in-charge at a second pharmacy if such a responsibility would interfere with his or her performance at the primary pharmacy.<sup>67</sup>

If a pharmacist-in-charge resigns from a pharmacy operation, the pharmacy may, on an interim basis, designate an employee pharmacist who is actively involved in the operation of the pharmacy as an interim pharmacist-in-charge. **This interim designation shall not exceed 120 days.** The Board shall be advised of this interim arrangement and the pharmacy, in the meantime, shall identify a permanent pharmacist-in-charge.<sup>68</sup>

Prior to September 2002, the pharmacist-in-charge could be held strictly liable for the acts of his or her employees acting within the scope of their employment whether or not the pharmacist-in-charge was aware of the pharmacy-related liability incurred. Presently, if the Board of Pharmacy is to discipline a pharmacist-in-charge for the violation of a state or federal law committed by another and the pharmacist-in-charge reported to the Board that violation, the Board shall use the report as a mitigating factor if all of the following are met:<sup>69</sup>

- The pharmacist-in-charge did not engage in any conduct that violated a pharmacy-practice related law.
- The pharmacist-in-charge did not permit, encourage, approve of, any conduct by another that resulted in the violation of a pharmacy-practice related law.
- The pharmacist-in-charge reported the violation to the Board in a timely manner.
- The pharmacist-in-charge took all necessary actions necessary to stop and remedy the violation within a reasonable period of time.

#### **PHARMACIST-IN-CHARGE NOTIFICATION** **TO THE BOARD**

A pharmacist-in-charge (PIC) to be selected, upon applying for PIC status, for a pharmacy operation, shall be

subject to approval by the Board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval and shall continue to name proposed replacements until a PIC is approved by the Board.<sup>70</sup>

If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the Board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the pharmacy, or the entity that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days.<sup>71</sup> The same approval process will also be applied to designated representatives-in-charge of wholesale or veterinary-drug/food operations.<sup>72</sup>

### ***WHAT ARE THE REQUIREMENTS FOR A REGISTERED PHARMACIST TO SERVE AS A PHARMACIST-PRECEPTOR?***

A “pharmacist-preceptor” is a licensed pharmacist who assumes the responsibility of supervising either intern pharmacists or pharmacy students enrolled in an “externship” (presently, more correctly referred to as an “Introductory Pharmacy Practice Experience [IPPE]”) or a “clerkship” (presently, more correctly referred to as an Advanced Pharmacy Practice Experience [APPE]) as part of their pharmacy school education. The purpose of serving as a pharmacist-preceptor is to train pharmacy interns or students to be proficient in the provision of pharmaceutical services. In serving as a pharmacist-preceptor, a pharmacist assumes responsibility for all pharmacy-related activities performed by the pharmacy intern or student while under that pharmacist’s supervision.<sup>73</sup>

In order for a licensed pharmacist to serve in a pharmacist-preceptor capacity, that pharmacist's license must not be revoked, suspended or on probation.<sup>74</sup>

### ***WHAT ARE THE CONTINUING EDUCATION REQUIREMENTS FOR A CALIFORNIA PHARMACIST?***

In order for a California registered pharmacist to be in compliance with the continuing education requirements of completing 30 hours of accredited C.E. each two years. The completion of that 30 hours must be done during the two year licensure period and no grace period is given by the Board to attain the full 30 hours beyond the two year requirement for C.E. if a deficiency in hours should exist. Certificates for C.E. hour completion must be retained for four (4) years.<sup>75</sup> If 30 hours of C.E. are not attained during the required two year period by the licensee, the Board has authority to place the pharmacist's license on an inactive status.

If the Board of Pharmacy conducts an audit or investigation to ensure a registered pharmacist has satisfactorily completed at least 30 hours of required C.E. programming in a two year licensure period, and that the audited pharmacist cannot show proof of at least 30 hours of required C.E. for the two year period, the Board shall cancel the active pharmacist license and issue an inactive pharmacist license. A licensee with an inactive pharmacist license may obtain an active pharmacist license by paying a re-renewal fee and submitting satisfactory proof to the Board that the licensee has completed 30 hours of required continuing education.<sup>76</sup>

### ***INACTIVE AND RETIRED PHARMACIST LICENSE DIFFERENCES***

In the September 2010 edition of the Board of Pharmacy's publication *The Script*, the Board distinguishes



the difference between an *inactive pharmacist license* and a *retired pharmacist license*.<sup>77</sup>

### An Inactive License:

- The pharmacist that has an inactive license is prohibited from practicing.
- The pharmacist notifies the Board that he or she wants his or her license inactive, which allows the pharmacist to retain a license, but disallows the pharmacist from practicing.
- The inactive license can be renewed every two years by paying the renewal fee, but no continuing education is required during this time if the licensee wishes to only continue his or her inactive status.
- An inactive license may be converted back to an active license at the time of renewal provided the licensee has fulfilled a minimum of 30 hours of the required continuing education during the previous two years. The additional requirement here is that the inactive licensee check the “Active Box” on the renewal form and attaching copies of certificates proving completion of the 30 hours
- No licensee whose license is revoked, suspended or placed on probation may obtain an inactive license.
- The Board will assign an inactive license status to the license of a pharmacist who fails to sign the renewal application or certify the completion of 30 hours of required continuing education. The Board will notify the licensee of either of these deficiencies, and if the deficiency is not corrected within 15 days of the Board’s notification, the licensee is placed on inactive status. This matter, can however be corrected if either or both of the issues described above are corrected.
- Inactive status is also assigned to a pharmacist who does not respond to the Board’s notification that a deficiency was noted during a C.E. audit by the Board.

### **A Retired License:**

- A retired license is issued to a pharmacist that wishes to retire from the practice of pharmacy.
- To regain an active license in this case, the retired pharmacist is required to fulfill all the requirements of a new application for licensure, and by taking both the NAPLEX and CPJE.

A pharmacist who does not renew his or her license, whether active or inactive, within three years of the license's expiration date will have his or her license cancelled.

### **PHARMACIST LICENSE RENEWAL REQUIREMENT**

When a California pharmacist receives his or her license renewal form, two major changes will have taken place that must be complied with:<sup>78</sup>

- There will be a space on the renewal form requesting disclosure of whether or not the licensee has been convicted of any violation of the law in this or another state, omitting traffic infractions under \$300 that do not involve alcohol, dangerous drugs, or controlled substances.
- Pharmacists licensed prior to 2002, when electronic fingerprinting was not available, will be notified that they need to resubmit fingerprint records to the Board before their license renewal date. The fingerprints to be submitted require that they be done through an electronic scanning system to be forwarded to the California Department of Justice. It is suggested that those who reside in California submit electronic fingerprints via "Live Scan." The Board has indicated that it will mail detailed instructions to pharmacists several months prior to the expiration date on their license. It is important to comply to this electronic fingerprint requirement to prevent delay in receiving your license renewal.

- Renewals will not be given unless the affected pharmacist submits an electronic fingerprint record. To not comply in a timely manner may cause a pharmacist to be working with an expired license.
- This same rule will over the next two or three years apply to pharmacy technician and designated representative license renewals as well.

Usually pharmacists licensed after 2002 were required to have electronic fingerprints on file. Thus, this ruling may only apply to pharmacists licensed before 2002 or who never had their fingerprints electronically set to record with the Department of Justice.

### ***WHAT ARE THE REQUIREMENTS AND RESPONSIBILITIES OF A PHARMACIST-INTERN?***

In order for an individual to receive pharmacist-intern status, he or she must either be currently enrolled or have completed required course work at a recognized (nationally accredited) school of pharmacy.<sup>79</sup> The State Board issues an intern card valid for up to six years if the applicant is currently enrolled in an accredited school of pharmacy.<sup>80</sup> Graduates (including foreign graduates) or out-of-state pharmacists may be granted two-year pharmacist-intern status in order to allow them to prepare for the California Pharmacy Examination. The internship may be extended at the discretion of the Board.<sup>81</sup> Generally the Board, at its discretion, allows the pharmacist-intern to extend the duration of the intern license up to two years beyond what is normally allowed for (usually the period of time that the intern is enrolled in an academic program or other circumstances where the Board grants a pharmacist-intern license) to enable the intern to complete the licensing requirements – usually the hours required in pharmacy practice-related areas.<sup>82</sup>

The Board applicant who is either an intern-pharmacist or a pharmacist registered in another state and who fails the licensure exam four times shall be required to successfully complete a minimum of 16 semester units of pharmacy education before being allowed to retake the board exam.<sup>83</sup> The pharmacist-intern in failing the Board four consecutive times in a row may have his or her intern license renewed for up to one year at the discretion of the Board provided the intern enrolls in a school of pharmacy and successfully passes the taking of the 16 units of structured course work approved by the Board within twelve months.<sup>84</sup>

The pharmacist intern is required to notify the Board within 30 days of any change of address, and in the case of a change in their intern license eligibility status, the intern must return his or her intern card by registered mail to the Board within 30 days of the change in eligibility.<sup>85</sup>

The pharmacist-intern may perform all those professional activities undertaken by the registered pharmacist, but only under the direct supervision of that pharmacist. It is a requirement for a pharmacist-intern to have experience in both community pharmacy and institutional pharmacy settings.<sup>86</sup> "An intern-pharmacist shall submit proof of his or her experience on Board approved affidavits, or another form specified by the Board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist-intern obtained the experience."<sup>87</sup> The pharmacist-intern must complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.<sup>88</sup>

One important fact that may distinguish a pharmacy intern's activities from a pharmacist's responsibilities is that at no time may a pharmacist intern be in possession of the key that opens and closes the pharmacy.<sup>89</sup>

A maximum of 600 hours may be granted by the Board through participation in "Introductory Pharmacy Practice Experience" (IPPE) and "Advanced Pharmacy



**Practice Experience” (APPE) programs provided by a school of pharmacy.<sup>90</sup>**

A statute passed in September of 2004 allows that one pharmacist may now supervise up to two pharmacist-interns at any given time.<sup>91</sup>

***MAY AN INTERN PHARMACIST HAVE DIRECT INVOLVEMENT IN PHYSICAL ASSESSMENTS AND EMERGENCY CONTRACEPTION PROTOCOLS?***

Regarding the question as to whether or not an intern pharmacist can be directly involved in Emergency Contraception (EC) protocols, doing skin punctures, the California Codes provide guidance:<sup>92</sup>

*“An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the supervision of a pharmacist.”*

Thus, an intern pharmacist can be involved in providing EC therapy, doing skin punctures, administering immunizations and performing routine physical assessments.<sup>93</sup> In association with these allowances, the intern pharmacist must meet other requirements such as receiving proper training to provide these services, following an approved protocol, and being under the direct supervision of the pharmacist who has also been trained to do the services described above, and who has already been participating in the provision of those services.<sup>94</sup>

***MUST ALL PHARMACY TECNICIANS BE REGISTERED WITH THE CALIFORNIA BOARD OF PHARMACY?***

Section 4115(e) of the California Business and Professions Codes requires that all pharmacy technicians be

registered with the Board of Pharmacy. This code now makes it mandatory for those pharmacy technicians who have been employed for years in institutional in-patient settings, and have not yet been formally certified, to apply for a registration application immediately. The purpose of this code is to ensure that there be both an accounting and standardization of pharmacy technicians regarding their training and also to allow the board to do criminal background checks.

### ***WHAT DUTIES MAY A PHARMACY TECHNICIAN PERFORM?***

The duties and responsibilities of a pharmacy technician are limited and may only be performed under the direct supervision of a registered pharmacist. Under no circumstances will the technician be allowed to make judgments concerning any matter related to pharmacy practice standards. Thus, the technician's involvement in pharmacy operations is restricted to the following 5 non-discretionary tasks/activities:<sup>95</sup>

1. Removing a drug or drugs from stock. This also includes controlled substances for the filling of controlled substance prescriptions by the pharmacy technician.<sup>91</sup>
2. Counting, pouring, or mixing pharmaceuticals.
3. Placing a product into a container.
4. Affixing a label or labels to the container.
5. Packaging and repackaging a product.

A task from the above list that might be challenged regarding whether or not discretion is involved is the "mixing of pharmaceuticals." The Board has not yet set any limits on this activity. In its broadest meaning, a pharmacy technician could conceivably be allowed to both weigh out and measure liquid volumes of pharmaceuticals, as well as mix or compound them into a final prescription product. The Board may view this activity as nondiscretionary, presumably based on its being both

repetitive and manipulative, and provided that the pharmacist has given definitive instructions to the technician on how to measure the ingredients and appropriately mix them together. In this manner, the pharmacist presumably has told the technician how to put the preparation together without the technician having to impose his or her own judgment. However, if the compounding task should require judgment by the technician, then the product preparation should be left to the pharmacist or pharmacist-intern.

***ARE PHARMACY TECHNICIANS NOW ALLOWED TO  
CHECK THE FILLING OF PATIENT MEDICATION  
ORDERS PREPARED BY OTHER PHARMACY  
TECHNICIANS?***

General acute care hospitals may now institute programs where the pharmacy technician may check the work of other pharmacy technicians under the following arrangements:

- The hospital must be a general acute hospital that has an ongoing clinical pharmacy program where pharmacists are deployed to the inpatient care areas to provide clinical services.<sup>96</sup>
- The pharmacy technicians may check the work of other pharmacy technicians in connection to the filling of floor and ward stock, and unit dose drugs to be provided to admitted patients whose orders have previously been reviewed and approved by the pharmacist.<sup>97</sup> Also, all compounded or repackaged products must be checked by the pharmacist before used for filling patient orders by the pharmacy technicians in the tech-check-tech program.<sup>98</sup>
- The pharmacy has on file a description of the clinical program prior to initiating pharmacy tech-check-pharmacy tech program.<sup>99</sup>
- The pharmacist-in-charge shall be the responsible party for ensuring that the tech-check-tech functions are

carefully monitored, and the program shall be under the direct supervision of a pharmacist whose supervision will be spelled-out in the hospital's policies and procedures along with ongoing evaluations of the program and the work performed by the pharmacy technicians involved.<sup>100</sup>

- A pharmacy technician who is assigned to the tech-check-tech program will receive specialized and advanced training as described in the hospital's policies and procedures.<sup>101</sup>

### ***PHARMACY TECHNICIAN EDUCATIONAL/TRAINING STANDARDS REQUIRED***

It is important for the community pharmacist to realize that the duties and responsibilities to be delegated to an employee functioning as a pharmacy technician may only be delegated if that employee is registered with and licensed by the Board of Pharmacy.<sup>102</sup>

A pharmacy technician license may be issued if the applicant is a high school graduate, or possesses a general educational development certificate equivalent, and meets any one of the following requirements:<sup>103</sup>

- Has obtained an associate's degree in pharmacy technology.
- Has completed a course of training specified by the Board. Such programs must have at least 240 hours of instruction covering material pertinent to the functions and responsibilities of a pharmacy technician.<sup>104</sup> The training program can be accredited by the American Society of Health System Pharmacists or provided by a branch of the federal armed services (must have a certificate of completion).<sup>105</sup>
- Has graduated from a school of pharmacy recognized by the Board.
- Is certified by the Pharmacy Technician Certification Board.



### ***WHAT REQUIREMENTS MUST BE SATISFIED FOR PHARMACY TECHNICIAN TRAINEES?***

The California Business and Professions Code, Section 4115.5 has incorporated an addendum regarding the experiential hours that must be completed by a pharmacy technician trainee. Accordingly, the pharmacy technician trainee shall participate in an externship program for not more than 120 hours when involved in a community or outpatient pharmacy experience, and not more than 200 hours when involved in a hospital pharmacy experience. Therefore, experience hours required if the trainee is to train in both a community and hospital pharmacy setting must be 320 hours. Furthermore, the externship period must not exceed 6 consecutive months in a community pharmacy and shall not exceed 12 months for a combined community and hospital pharmacy experience.<sup>106</sup>

The pharmacy technician trainee participating in an externship shall wear identification that indicates that he or she is a student trainee.<sup>107</sup>

### ***RATIO OF PHARMACY TECHNICIANS TO PHARMACISTS AND OTHER CRITERIA THAT MUST BE MET***

In a community pharmacy setting, a single pharmacist may only have **one pharmacy technician** assigned to him or her.<sup>108</sup> A second pharmacist may now have **two pharmacy technicians assigned to him or her.**<sup>109</sup> Thus, when two pharmacists are working together at the same time in a retail pharmacy operation, there may now be a total of three **(3)** licensed technicians present. Additional pharmacists within the same retail operation may also have two pharmacy technicians assigned to them as well. The second pharmacist may refuse to supervise an additional pharmacy technician by notifying the pharmacist-in-charge (PIC) in writing indicating the reason for refusal. This notification to the PIC must be in writing and submitted within a reasonable period, not to exceed 24 hours after a job

schedule is posted indicating the times when a second technician is to be assigned.<sup>110</sup>

There is, however, an exception to the one pharmacist on duty at a time rule only having one pharmacy technician. If a community pharmacy is engaged in the filling of inpatient orders for a licensed health facility or a patient of a licensed home health agency, then that community pharmacy may have two pharmacy technicians per the one pharmacist on duty at the time when such inpatient or home health agency prescriptions are being prepared.<sup>111</sup> Once the task of filling the inpatient orders is completed, then the ratio of only one technician to a single pharmacist must be maintained. Upon the completion of the inpatient tasks, the second technician may not continue to perform the duties of a pharmacy technician if only one pharmacist is on duty, but may assume the duties ordinarily delegated to a pharmacy clerk.

The pharmacy technician is required to wear identification clearly identifying him or her as a pharmacy technician.<sup>112</sup> If the technician assumes clerical activities in order to comply with the legally allowable pharmacist-to-technician ratio, then the technician's identification badge must be removed.

A pharmacy that employs a pharmacy technician must develop a job description and written policies and procedures that ensure compliance with the job duties which the law allows the pharmacy technician to perform. Records must be kept for at least 3 years showing that the pharmacy technician's duties were in compliance with the stated job description and the policies and procedures for a pharmacy technician.<sup>113</sup>

At present, no board examination or testing requirement has been implemented for the certification of pharmacy technicians in California. However, the Board of Pharmacy is seriously considering enacting regulations that will require new pharmacy technician candidates to take a "Certification Examination" and to take continuing

education courses similar to the pharmacist requirement in California.

### ***PHARMACY CLERK REQUIREMENTS***

There are no set ratios regarding the number of pharmacy clerks for each pharmacist. The pharmacy may employ clerks or non-licensed personnel to type prescription labels, enter prescription information into the pharmacy's electronic record-keeping system, and to request and receive refill authorizations.<sup>114</sup> The supervising pharmacist who initials the prescription or prescription record for each patient is still responsible for the accuracy of the prescription information and the dispensed prescription.<sup>115</sup> Other pharmacy clerks may be available to stock drugs, answer some phone calls or ring up prescription sales.

Under normal circumstances, a single pharmacist on duty may have the following ancillary personnel working at any given time:

- Two pharmacy interns;
- One pharmacy technician (two pharmacy technicians are allowed if the duties involve inpatient pharmacy activities). For each additional pharmacist on duty, two pharmacy technicians can be assigned (therefore, if there are three pharmacists on duty at one time, there may be a total of five technicians); and
- Any reasonable number of clerks to perform the functions described above.

Concerning the delegation of responsibilities as described above, a pharmacist may supervise the number of non-licensed personnel performing the duties noted, if that pharmacist determines in the exercise of his or her professional judgment that the delegation of such duties does not interfere with the effective performance of the pharmacist's responsibilities under the pharmacy laws.<sup>116</sup>

**CALLING FOR REFILLS BY PHARMACY TECHNICIANS  
AND PHARMACY CLERKS**

When a prescription for a non-controlled substance medication has no further refills it is allowable to have the pharmacy technician or the pharmacy clerk call the prescriber's office for continuation of the medication by requesting the issuance of more refills. Usually the technician or the clerk asks the prescriber or an authorized representative from the prescriber's office, with permission from the prescriber, to allow for a continuance of the medication by asking for both a refill of the medication and a designation on how many additional refills will be allowed. If the prescriber or their representative make any change from the way the prescription was previously written (e.g. change the strength, the dosing frequency or the drug itself) then either the pharmacist or pharmacist intern must take over the phone call and record any changes that are made on the original order since this now becomes a new prescription (requiring the modified prescription to be rewritten).

Technically, if the non-scheduled drug prescription to be refilled is greater than a year old, the call to renew the prescription really falls into the category of a new prescription, since the prescription should be rewritten and processed as a new prescription. Since, by operation of the law, the prescription falls into the category of a "new prescription" it must be rewritten, and the request for continuance should only be done by the pharmacist or the pharmacist intern.

The same is true for refilling Schedule III or IV controlled substance prescriptions where they may become new prescriptions. Thus, each time the Schedule III or IV prescription is to be renewed if it exceeds six months, 5 refills, or 120 days of refills, it then is considered to be a request for a "new prescription" that needs to be rewritten if the request to continue is granted by the prescriber. Phoning and rewriting a prescription for the continuance of a Schedule III or IV controlled substance based upon the



above situations should be undertaken by either a pharmacist or a pharmacist-intern, and not a technician or a clerk.

***WHAT IS A "REPRESENTATIVE" AND  
"REPRESENTATIVE-IN-CHARGE" STATUS IN  
RELATIONSHIP TO A VETERINARY FOOD-ANIMAL  
DRUG RETAIL OPERATION OR DRUG WHOLESALER?***

The California Board of Pharmacy is presently the licensing agency for veterinary food-animal drug retail operations and drug wholesalers as well as for pharmacy operations. Since the operations of a veterinary food-animal drug retail business and a drug wholesaler are under the Pharmacy Board's licensing authority, and since neither require a pharmacist to be in charge or operate such activities, the individual in charge of such operations is designated as a "Representative-In-Charge" (previously referred to as an "Exemptee-In-Charge") or is serving as an employee of such operations, that person is designated as a "Representative" (previously referred as an "Exemptee").<sup>117</sup> Under the non-pharmacist "representative or exemptee" status associated with the operation of a veterinary food-animal drug retail facility or a drug wholesaler operation, the following is required:<sup>117</sup>

- An annual license shall be acquired from the State Board of Pharmacy.
- There shall be designated on an application to the Board who shall serve as the "representative-in-charge." Notification to the Board of a new "representative-in-charge" must occur within 30 days of the date that the prior "exemptee-in-charge" ceases his or her position of being in charge.
- The assignment of a new "representative-in-charge" must have the approval of the Board. If a recommended "representative-in-charge" is disapproved, the veterinary food-animal drug retailer shall propose another replacement within 15 days of the date of disapproval,

**and shall continue to name proposed replacements until a designated representative-in-charge is approved by the Board.**

REFERENCES TO CHAPTER 3

1. Calif. Bus. & Prof. Codes, Sec. 4001[a][b]
2. *Ibid.* at Sec. 4001[b]
3. *Ibid.* at Sec. 4001[c]
4. *Ibid.* at Sec. 4001[c]
5. *Ibid.* at Sec. 4001[d]
6. *Ibid.* at Sec. 4002[b]
7. *Ibid.* at Sec. 4002[b]
8. *Ibid.* at Sec. 4005[c]
9. *Ibid.* at Sec. 4008[a]
10. *Ibid.* at Sec. 4008[b]
11. *Ibid.* at Sec. 4008[c]
12. *Ibid.* at Sec. 4082
13. *Ibid.* at Sec. 4332, & Calif. Health & Safety Codes, Sec. 11195
14. Calif. Bus. & Prof. Codes, Sec. 4003[a]
15. Title 16, Calif. Code of Regs., Sec. 1703
16. Calif. Bus. & Prof. Codes, Sec. 4059[a] & Calif. Health & Safety Codes, Sec. 11150
17. Calif. Bus. & Prof. Codes, Sec. 4170[c]
18. Calif. Bus. & Prof. Codes, Secs. 4040 & 4060, & Calif. Health & Safety Codes, Sec. 11150
19. Calif. Bus. & Prof. Codes, Secs. 4052[a], 4052.1 & 4052.2
20. *The Script*, Oct. 2005 Ed., pg 11.
21. North Carolina Board of Pharmacy Rule .1815
22. PA Code, Sec. 27.18[h] Standards of Practice
23. Calif. Bus. & Prof. Code. Sec. 3041[a][c]
24. *Ibid.* at Sec. 3041[a][b][c][f]
25. Calif. Bus. & Prof. Code, Sec. 3041
26. *Ibid.* at Sec. 3640.5 & *The Script*, Oct, 2005 Ed., pg. 11.
27. Calif. Bus. & Prof. Code, Sec. 3640.5[e]
28. *Ibid.* at Secs. 3640-3645 & *The Script*, Oct, 2005 Ed., pg. 11.
29. Calif. Bus. & Prof. Codes, Secs. 3640.5[f], 3640.7, & *The Script*, Oct, 2005 Ed., pg. 11.
30. Calif. Bus. & Prof. Codes, Sec 3502.1
31. Calif. Bus. & Prof. Codes, sec. 3502.1[d]

32. Calif. Health & Safety Codes, Sec. 11150 & Calif. Bus. & Prof. Codes, Sec. 3502.1(b) & *The Script*, Feb. 2009, pg. 11.
33. *Ibid* at Secs. 11161.5[a][b] & 11164[a]
34. Calif. Bus. & Prof. Codes, Sections 2746.51[b][3] & 2836.1[f][2]
35. Calif. Bus. & Prof. Codes, Sec. 4076[a][4]
36. *Ibid.* at Sec. 4170[a][8]
37. *Ibid.* at Sec. 4061[a]
38. Calif. Bus. & Prof. Codes, Secs. 2725 & 2836.1
39. *Ibid.* at Sec. 2836.1
40. *Ibid.* at Sec. 2725 & 2746.51
41. Calif. Bus. & Prof. Codes, Secs. 2725.1 & 2746.51, and Calif. Health & Safety Codes, Secs. 11026 & 11150
42. Calif. Bus. & Prof. Code, Sec. 2725.1 and Calif. Health & Safety Code, Secs. 11026 & 11150
43. Calif. Health & Safety Code, Sec. 11164[a]
44. Calif. Bus. & Prof. Code, Sec. 2746.51[b][2]
45. *Ibid.* at Sec. 2746.51
46. Calif. Health & Safety Code, Sec. 120582[a][b]
47. See Calif. Board of Pharmacy *Script*, Oct. 2003, pg. 8
48. Calif. Bus. & Prof. Code, Secs. 3516[b] & 2836.1[e]
49. Calif. Bus. & Prof. Code, Sec. 2746.51
50. *Ibid.* at Sec. 4076[a][4]
51. Calif. Health & Safety Code, Sec. 120582[a][b]
52. Calif. Bus. & Prof. Code, Sec. 4061[a]
53. Title 16, Calif. Code of Regs, Sec. 1793.1
54. Calif. Bus. & Prof. Codes, Sec. 4052[a][3]
55. *Ibid.* at Sec. 4052.4 (also see Calif. Bus. & Prof. Codes, Secs. 2038 & 2052)
56. *Ibid.* at Sec. 4052.4
57. *Ibid.* at Sec. 4103
58. *Ibid.* at Sec. 4103
59. *Ibid.* at Sections 4052[a][9] & 4052.3
60. *Ibid.* at Secs. 4052[a][5] & 4052.1
61. Calif. Bus. & Prof. Code, Secs. 4052.1[a][4] & 4052.2[a][4]
62. Title 16, Calif. Code of Regs, Sec. 1709[a]



63. Calif. Bus. & Prof. Codes, Secs. 4101[a], 4113[a][c]. and Title 16, Calif. Code of Regs., Sec. 1709[a]
64. Title 16, Calif. Code of Regs, Sec. 1709.1[c]
65. *Ibid.* at Sec. 1709.1[c]
66. *Ibid.* at Sec. 1709.1[d]
67. *Ibid.* at Sec. 1709.1[f]
68. *Ibid.* at Sec. 1709.1[e]
69. Calif. Bus. & Prof. Codes, Sec. 4306.6
70. *Ibid.* at Sec. 4113[d]
71. *Ibid.* at Sec. 4113[e]
72. *Ibid.* at Sec. 4160[d][e]
73. Title 16, Calif. Code of Regs, Sec. 1726
74. *Ibid.* at Sec. 1773[a][6]
75. *Ibid.* at Sec. 1732.5
76. Calif. Bus. & Prof. Codes, Sec. 4231[d]
77. *Ibid.* at Sections 701, 4200.5, 4231[c][d], 4402[a][b][c] and the Sept. 2010 *Script* (a publication of the Calif. State Board of Pharmacy)
78. Title 16, Calif. Code of Regs., Sec. 1702
79. *Ibid.* at Sec. 1719
80. Calif. Bus. & Prof. Code, Sec. 4208[a][1]
81. *Ibid.* at Sec. 4208[a][2][3]
82. *Ibid.* at Sec. 4208[e]
83. Title 16, Calif. Code of Regs., Sec. 1725[c], & Calif. Bus. & Prof. Code, Sec. 4208[a][4]
84. Calif. Bus. & Prof. Code, Sec. 4208[a][4] & 4200.1
85. Calif. Bus. & Prof. Code, Sec. 4208[c][d]
86. Title 16, Calif. Code of Regs., Sec.1728[a][1][(C)], & Calif. Bus. & Prof. Code, Sec. 4114[a]
87. Calif. Bus. & Prof. Code, Sec. 4209[b]
88. *Ibid.* at Sec. 4209[a][1]
89. Title 16, Calif. Code of Regs., Sec. 1714[d]
90. *Ibid.* at Sec. 1728[a]
91. Calif. Bus. & Prof. Code, Sec. 4114(b)
92. *Ibid.* at Sec. 4114[a]
93. *Ibid.* at Secs. 4052[a][8][9], 4052.1, 4052.3, 4052.4, 4115 & Title 16, Calif. Code of Regs., Sec. 1793.1
94. The *Script*, Oct. 2005 Ed., pg. 10 & Calif. Bus. & Prof. Code, Sec. 4114[a]

95. *Ibid.* at Sec. 4115[a] & Title 16, Calif. Code of Regs, Sec. 1793.2
96. Title 16, Calif. Code of Regs., Sec. 1793.8[a]
97. *Ibid.* at Sec. 1793.8[a]
98. *Ibid.* at Sec. 1793.8[b]
99. *Ibid.* at Sec. 1793.8[a]
100. *Ibid.* at Sec. 1793.8[c]
101. *Ibid.* at Sec. 1793.8[c]
102. Calif. Bus. & Prof. Codes, Sec. 4115[e]
103. *Ibid.* at Sec. 4202[a]
104. Title 16, Calif. Code of Regs., Sec. 1793.6[c]
105. *Ibid.* at Sec. 1793.6[a][b]
106. Calif. Bus. & Prof. Codes, Sec. 4115[c][d]
107. *Ibid.* at Sec. 4115[f][2]
108. *Ibid.* at Sec. 4115[f][2]
109. *Ibid.* at Sec. 4115[f][2]
110. *Ibid.* at Sec. 4115[f][3]
111. Title 16, Calif. Code of Regs., Sec. 1793.7[f]
112. *Ibid.* at Sec. 1793.7[c]
113. *Ibid.* at Sec. 1793.7[d]
114. *Ibid.* at Sec. 1793.3[a][b]
115. *Ibid.* at Sec. 1793.3[a]
116. *Ibid.* at Sec. 1793.3[b]
117. Calif. Bus. & Prof. Code, Secs. 4022.5 & 4196

# CHAPTER 4

## GENERAL PHARMACY PRACTICE CONCERNS AND PROFESSIONAL CONDUCT ISSUES

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***IS A PHARMACIST ALLOWED TO FURNISH CERTAIN  
PRESCRIPTION DRUGS OR DEVICES TO HEALTH CARE  
PERSONNEL WITHOUT A PRESCRIPTION WHO ARE  
NOT AUTHORIZED LICENSED PRESCRIBERS?***

There are limited circumstances whereby a pharmacist may furnish prescription drugs or devices to licensed health care providers who do not qualify as licensed physicians, dentists, podiatrists, optometrists, veterinarians or naturopathic doctors. Optometrists who have special certification are allowed to prescribe certain prescription drugs for patients as noted in the previous chapter.<sup>1</sup>

A pharmacist may furnish a dangerous drug or device to a physical therapist as long as that drug or device is common to the specific services these health care professionals render to patients.<sup>2</sup> If such drugs or devices are provided, the pharmacist must keep a record containing the date of the transaction, the name and address of the physical therapist, and the name and quantity of the drug or device provided.<sup>3</sup>

As an example, in the case of physical therapists, prescription medical devices such as electroneuromyographic needle electrodes or hypodermic needles used for the purpose of placing wire electrodes for "kinesiographical electromyographic" testing may be furnished by a pharmacist, provided that such devices are necessary in the performance of a service expected or required of a physical therapist.<sup>4</sup> Transaction records showing the provision of such devices must be kept by the pharmacy indicating the date of the transaction, name and address of supplier and the buyer, and a description of the device and quantity supplied.<sup>5</sup>

***WHO MAY PHONE IN A PRESCRIPTION  
FROM A PRESCRIBER'S OFFICE?***

If the prescriber does not phone in the order, he or she may designate his or her employee to orally or

electronically transmit a prescription to the pharmacy. An emergency Schedule II controlled substance prescription may only be called in by the prescriber.<sup>6</sup> Technically, any employee of the prescriber may call in the prescription with the exception of Schedule II controlled substances. The party receiving the oral order must record the name of the employee of the prescriber who transmitted the order, and shall make a reasonable effort to determine that the party transmitting the prescription is authorized to do so.<sup>7</sup> The pharmacist need not reduce to writing the address, telephone number, license classification, federal registry number, or the address of the patient, if such information is readily retrievable in the pharmacy.<sup>8</sup>

#### ***MAY PRESCRIPTIONS FROM PRESCRIBERS BE ELECTRONICALLY TRANSMITTED TO A PHARMACY?***

The rules on sending prescriptions electronically have gone through several changes and reconsiderations. It is anticipated that further additions and clearer points of understanding regarding electronic prescribing will take place in the near future to counter a pharmacist's confusion and misunderstandings associated with this area of prescription transmission. The following brief discussion hopefully will give some clarity for this method of prescribing. You may wish to contact the Calif. Board of Pharmacy for further clarification if needed.

According to the Board of Pharmacy "an electronic transmission prescription includes both 'image' and 'data' prescriptions." "Electronic image transmission prescription means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. Electronic data transmission prescription means any prescription order, other than an electronic image transmission prescription, electronically transmitted from a licensed prescriber to a pharmacy."<sup>9</sup>

If a non-scheduled drug prescription is transmitted by a prescriber using his or her computer and sent to a pharmacy's computer or to its fax machine, (an "electronic data prescription,") the transmitted prescription will require a digital signature to be entered onto the prescription by the prescriber. If the prescription is faxed by the prescriber to the pharmacy's fax machine (an "electronic image prescription") it will require that the prescriber write his or her signature on the faxed prescription before faxing.<sup>10</sup>

Data transmitted prescriptions for non-scheduled drugs sent from a prescriber's office that have an authentic digital prescriber signature, may be stored in the pharmacy's computer system.<sup>11</sup> According to Calif. Bus. & Prof. Code, Sec. 4070[b] an electronic data transmission prescription for a non-scheduled drug does not need to be reduced to writing by the pharmacist, as long as the pharmacy is able, upon request by the Board, to immediately produce a hard copy of the prescription from its computerized data bank.<sup>12</sup>

In the case where there is to be a change or modification of a computerized pharmacy record after the drug has been dispensed and after the pharmacist enters a change or enters his or her approval of the change, the following shall occur:<sup>13</sup>

- The date shall be entered when the change was made.
- The identity of the person or pharmacist making the change.
- The identity of the pharmacist approving the change.

Schedule III, IV, and VI controlled substance drugs that are transferred by either electronic data or image transmission can be treated like oral prescriptions as long as they are authenticated and validated with the prescriber's digital (for data transmission) or written signature (for image transmission). As a practical matter electronically transmitted prescriptions for Schedule III, IV or V controlled substances (specifically those involving data transmission) are to be treated like an oral prescription



order, and therefore converted to hard copies using the pharmacy's prescription blanks.<sup>14</sup> The name of the party electronically transmitting the Schedule III, IV, or V controlled substance prescription must be on the transmitted prescription.<sup>15</sup> It is important to note that Schedule III, IV, or V controlled substance prescriptions cannot be transmitted from a computer to a pharmacy fax or to a pharmacy computer for storage (the latter only if in association with the federal "E-Prescribing" Program).<sup>16</sup>

Schedule II, III, IV, & V controlled substances cannot be transmitted by electronic transmission, and computer stored, unless the federal rules on E-Prescribing are followed. Under the federal rules, if a pharmacy is registered and certified to receive controlled substance prescriptions electronically by means of the E-Prescribing Program it may receive Schedule II, III, IV, and V from certified prescribers, and may maintain such controlled substance prescription records electronically. It is important to note that the DEA has established rules on E-prescribing that pertain to controlled substance prescribing that will allow for all controlled substances, including Schedule II's, to be electronically transferred from a prescriber's office to a pharmacy if both have the proper certification to both transmit and receive controlled substance prescriptions. E-prescribing involving controlled substances is discussed in greater detail in Chapter 14.

In the case where there is to be a change or modification of an E-Prescription computerized pharmacy record after the drug has been dispensed and after the pharmacist enters a change or enters his or her approval of the change, the following shall occur:<sup>17</sup>

- The date shall be entered when the change was made.
- The identity of the person or pharmacist making the change.
- The identity of the pharmacist approving the change.

***WHO MAY PHONE IN A PRESCRIPTION  
ORDER FROM A HEALTH CARE FACILITY?***

In addition to the prescriber's office, there are specific personnel who, if authorized by an administrative directive, may orally or electronically transmit a prescription order to a pharmacy from a licensed skilled nursing facility, or from an intermediate care or other health care facility. The list of personnel authorized to orally or electronically transmit a prescription from a prescriber may include a registered pharmacist, a registered nurse, a licensed vocational nurse, a licensed psychiatric technician, or other healing arts licentiates.<sup>18</sup> The party orally or electronically transmitting the prescription order may either be a consultant to the facility or be employed by the facility. He or she must be authorized by means of an administrative written procedure to forward prescription orders to a pharmacy. Again, the receiving pharmacy must record the name of the person transmitting the order, and take appropriate steps to determine that the person transmitting the prescription is authorized to do so. The transmission of orders for Schedule II controlled substances will not apply to persons who are not licensed prescribers.<sup>19</sup>

***WHO MAY RECEIVE AN ORALLY TRANSMITTED  
PRESCRIPTION ORDER FROM A LICENSED  
PRESCRIBER'S OFFICE?***

An orally transmitted new prescription from a prescriber's office may be received by either a pharmacist or a pharmacist intern. Promptly upon receipt of an orally transmitted prescription, the pharmacist must commit it to writing, initial it, and identify it as an orally transmitted prescription with the name of the party who transmitted it.<sup>16</sup> If the prescription is dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription.<sup>20</sup>

It should be noted that if the prescriber's office is simply calling to transmit a refill number from an old

prescription, then a clerk or pharmacy technician can receive the refill number information. Also, at the direction of the pharmacist, a non-licensed person (such as a clerk) may request and receive refill authorization from a prescriber's office.<sup>21</sup> Only the pharmacist and pharmacist intern can take a new prescription over the phone, or a modification of an existing prescription order.<sup>22</sup>

***MAY A PHARMACIST FILL A PRESCRIPTION FROM ANOTHER STATE OR FROM OUT-OF-COUNTRY?***

A pharmacy in California may fill prescriptions issued by licensed prescribers located in other states.<sup>23</sup> Prescriptions for Schedule III, IV, and V controlled substances may also be dispensed by California pharmacies if received from out-of-state prescribers who write prescriptions for these controlled substances in a manner that conforms "with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed."<sup>24</sup> Since Schedule III, IV, and V controlled substance prescriptions can be called in from out-of-state prescribers, the California security prescription form need not be used since the prescription can be transferred by the pharmacist onto the pharmacy's blank prescription pads.<sup>25</sup>

As a general rule, a pharmacist should not fill a prescription from another country since the pharmacist would need to know if the product is approved for use in that country by an equivalent agency like the FDA, and that the laws governing the filling of prescriptions are clearly understood by the pharmacist in California to suggest that there is legal authority to have the prescription from another country filled in California. There are states such as Texas that will allow for the filling of out-of-country prescriptions, but under very rigid rules. There are however laws, both state and federal, that allows for the filling of prescriptions from the District of Columbia and the U.S. territories which

include Puerto Rico, the Virgin Islands, Guam, and American Samoa.

These exceptions are noted in the following codes:

- CA Bus. & Prof. Code, Sect. 21: "State" means the State of California, unless applied to the different parts of the U.S. In the latter case, it includes the District of Columbia and the territories.<sup>26</sup>
- 4 USC, Sec. 110(d): The term "State" includes any Territory or possession of the United States. (Major U.S. recognized territories are Guam and the Virgin Islands are organized territories, but they are neither incorporated nor considered commonwealths. On the other hand, American Samoa is formally considered an unorganized territory, though it is self-governing under a 1967 constitution.)<sup>27</sup>
- Title 16, Calif. Code of Regs., Sec. 1717(d) allows for the filling of out-of-state prescriptions, and in accordance with Calif. Bus. & Prof. Code 4005.<sup>28</sup>

### ***WHAT IF A PRESCRIPTION DRUG DOES NOT CONTAIN AN EXPIRATION DATE?***

Generally any prescription drug not bearing a manufacturer's expiration date is considered under the law to have expired and may not be dispensed pursuant to a patient's prescription.<sup>29</sup> A drug product without an expiration date has no business in the pharmacy's stock and should either be 1) destroyed, or 2) sent back to the supplier. There is however a limited exception to having an expiration date on a drug product. No expiration date is required for human over-the-counter drug products if the product's labeling does not bear dosage limitations and the drug product is stable for at least three years if supported by appropriate stability data.<sup>30</sup>



## **WHAT EXPIRATION DATES CAN APPEAR ON A PRESCRIPTION?**

The following represent the general rules regarding the placement of expiration dates on prescription drug labels or drug product labels prepared by the pharmacy such as non-sterile compounded drugs or extemporaneously prepared unit dose packages:

For products produced by the drug manufacturer: The dispensing pharmacist may use either the exact expiration date imprinted on the drug manufacturer's container or possibly a one year expiration date or a reasonable date from the date the drug is dispensed unless the manufacturer's date is earlier.<sup>31</sup> In dispensing a prescription drug, the pharmacist must be cautioned to not dispense a product whose expiration date (as it appears on the manufacturer's label) is fine at the date of dispensing the medication, but will expire at some point during the course of therapy (example: The drug expires on June 20xx [meaning it expires at the end of the month] and it is presently June 1, 20xx when the prescription is filled. The patient is given a 3 month supply of the drug with the June 30, 20xx expiration date. Under this circumstance, the drug will have expired on June 30, 20xx with 2 months of the drug remaining during the expired period. This would be providing the drug "*Beyond its Use Date.*")

While it is not law, at least not yet, a pharmacist might consider removing any drug stock that has less than a two to three month remaining expiration date on the drug manufacturer's label.

For compounded non-sterile and sterile products: The dispensing pharmacist may use a six month expiration date from the date the product is compounded, unless any of the ingredients used are less than the six month expiration date – then that date is to be used.<sup>32</sup> Usually a sterile compounded product may have an expiration date less than six months. Again, the term "*Beyond Use Date*" is also applied to compounded products, suggesting that the product should



not be used in the case of most compounded products beyond 6 months. However, some compounded products based upon their stability may have a shorter “*beyond use date*.” The following factors should be taken into account for compounded products when the pharmacist dispenses the drug in considering the “*Beyond-use date*”:<sup>33</sup>

- Conditions of storage by the patient.
- Type of packaging.
- Nature of drug being dispensed
- Frequency with which the package may be opened.
- Manufacturer’s expiration date.

For extemporaneous preparation of unit dose drug packaging: The expiration date placed on the extemporaneously prepared unit dose package may be one year or less if the expiration date on the manufacturer’s package is less than one year.<sup>34</sup>

### ***MAY A PHARMACIST FILL A PREPRINTED, MULTIPLE CHECKOFF PRESCRIPTION THAT HAS MORE THAN ONE DRUG ITEM CHECKED-OFF?***

Because of the specialty of some prescribers or the limited number of drugs they may use in practice, it is not uncommon for such prescribers to have *Preprinted, Multiple Check-Off Prescription Blanks*. These blanks will have anywhere from two to perhaps as many as 10 preprinted drug names, with strengths, and possibly quantity and directions, ready to be simply checked-off by the prescriber. While this practice may be convenient for the prescriber, there is always a fear that the patient may tamper with these forms by ordering other drugs on the list without the consent of the prescriber. Two important considerations regarding the use of these preprinted, multiple check-off prescriptions are the following:

- No person shall dispense a controlled substance pursuant to a preprinted, multiple check-off prescription blank if the prescription does not

comply with the special security requirements.<sup>35</sup> Thus, if a controlled substance, specifically Schedule III, IV, or V controlled substances, is preprinted onto a multiple check-off prescription form that is not a special security prescription form, even if it is the only drug checked-off, it may not be filled as such. To be filled correctly, the prescriber should be contacted to validate the request for the controlled substance and that information transferred in the handwriting of the pharmacist to a pharmacy prescription blank, or otherwise it should be in the handwriting of the prescriber or preprinted on a special security prescription form.

- The law pertaining to preprinted, multiple check-off prescriptions only allowed one non-scheduled drug to be checked-off to be valid and honored by the pharmacist prior to August, 2001. Since then the law has been changed and now states the following:<sup>36</sup>

*“A person may dispense a dangerous drug, that is not a controlled substance, pursuant to a preprinted, multiple check-off prescription blank and may dispense more than one dangerous drug... pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs he or she has prescribed.”*

#### **ARE THERE REFILL LIMITS ON A PRESCRIPTION THAT HAS A “PRN REFILL” DESIGNATION**

A 1995 State Attorney General opinion strongly recommends that all nonscheduled prescriptions containing a “prn refill” designation may be refilled, where appropriate and reasonable, within one year or less from the date the prescription was written without contacting the prescriber.<sup>37</sup> The prescriber needs to be contacted after a year where a “prn” refill designation is noted on the prescription. Having

the use of “prn” in the directions (e.g. “take prn”) for a non-controlled substance prescription is allowable as long as the patient has been informed and understands how to take the medication.

A “prn” refill designation for Scheduled III, IV, or V controlled substances is not acceptable.<sup>38</sup> A specific number of refills up to **five (5) times** must be clearly stated in the refill column after confirming the number with the prescriber. Also, the directions on the controlled substance prescription must be clear.<sup>39</sup> Thus, as an example, “one tablet prn” is inadequate, whereby the frequency of use needs to be confirmed by the prescriber (e.g. “one tablet every 4 hours prn pain.”) This way the chance for misuse or abuse is better monitored in accordance with clear directions provided by the prescriber.

In the case of where the prescriber is unavailable to approve of a refill request for both non-scheduled as well as Scheduled controlled substances, the law does allow the pharmacist, based upon sound judgment, to provide the patient with the medication under certain conditions. This aspect of issuing the medication where no refills are indicated, will be discussed in *Chapter 6* under the heading, *“Pharmacist Discretion In Providing Emergency Supplies Of Drugs Without Refill Authorization”* (the discussion under this heading considers two possibilities: 1) general emergency need of the prescription medication when the prescriber is unavailable to authorize a refill, and 2) provision of prescription medications during a *Declared State of Emergency*.) When the medication is provided under an emergency circumstance, the pharmacist shall inform the prescriber of the refill dispensed within a reasonable period of time.<sup>40</sup> The pharmacist shall also maintain a record of providing the refill and the basis for his or her judgment in providing the patient with the refill prescription.<sup>41</sup>

**MAY A PHARMACIST DEVIATE FROM THE  
WAY A PRESCRIPTION IS WRITTEN?**

A pharmacist shall not deviate from filling a prescription as it is written unless the prescriber is contacted to authorize the change.<sup>42</sup> However, a pharmacist may dispense less of a prescribed medication than is called for by the prescription if he or she deems it necessary. In such a case the pharmacist must contact the prescriber in order to fill the prescription for the reduced amount. For example, a physician might order 100 capsules of a hypnotic controlled substance. If the pharmacist is concerned that the patient may abuse the drug, he or she must call the prescribing physician to discuss any concerns and obtain the prescriber's approval to change the amount prescribed or dispensed.

It is important to note that in the last sentence of the regulation restricting deviation from the written prescription there is suggestion that the pharmacist can possibly exercise some discretion in this area. The wording in the last sentence of this regulation states, "*Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly accepted pharmaceutical practice in the compounding or dispensing of a prescription.*"<sup>43</sup> Perhaps this sentence can be applied to a common practice issue where the prescriber writes for an amount of drug that exceeds the number of days that are reimbursable by the patient's health care insurance plan. Rather than call the prescriber for an okay to decrease the amount from what is written, the pharmacist may take it upon him- or herself to adjust it so that the amount provided will equilibrate to what the insurance carrier will cover. Whether or not this example falls in the area of "commonly accepted pharmaceutical practice" may be open to challenge. Because of the discrepancy issue when it comes to what the insurance company will reimburse for which may limit the patient from getting the amount the prescriber ordered, the California legislature has considered giving the pharmacist discretion in this area without having to contact the prescriber each time in order to dispense the



amount covered by the insurance company and placing the remainder under a refill arrangement.

***MAY A PHARMACIST REFUSE TO FILL A  
PRESCRIPTION BASED UPON RELIGIOUS,  
MORAL OR ETHICAL CONCERNS?***

California Business and Professions Code, Section 733(b)(3) allows for California pharmacists, based upon religious, moral or ethical grounds, to refuse to fill a given prescription for a drug or device prescribed for a patient. The usual category of drug product agents involved are contraceptive agents. While the law makes it clear that a pharmacist shall not obstruct a patient from obtaining a prescription drug or device, that pharmacist may refuse the filling of a given prescription item if that pharmacist originally notifies his/her employer of the objection and that pharmacy, pharmacist or employer makes reasonable accommodations to ensure that the patient obtains the prescription item in a timely manner.<sup>44</sup>

The pharmacist who refuses to fill a prescription for a given class or classes of drugs or devices and upon notifying his/her employer in writing at the time of being employed or at a time when such religious, moral or ethical concerns arise, then the employer must establish written policy setting forth the procedures that will ensure that the patient will receive the prescribed drug or device in a timely and reasonable manner.<sup>45</sup> Such a policy is intended to state other alternative measures that can be taken to ensure that the patient is provided his or her drug or device without an unreasonable delay. Such alternatives would probably include arrangements with another employee pharmacist filling the prescription, dispensing it and providing counseling; or having another pharmacy in the immediate area fill the prescription in order to have it ready for the patient to pick-up or arranged to be delivered to the patient's home or business.



If a written policy with procedures does not exist and a pharmacist refuses to fill a given prescription based upon his or her religious, moral, or ethical beliefs, and further offers no reasonable alternatives to accommodate the patient, the Board may view such action on the part of the pharmacy and pharmacist as “obstructing a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by the Board of Pharmacy.”<sup>46</sup>

***RESPONSIBILITY OF A PHARMACIST DURING OTHER SITUATIONS WHERE HE/SHE REFUSES TO FILL A PRESCRIPTION OR DOES NOT HAVE THE MEDICATION IN STOCK IN ORDER TO FILL THE PRESCRIPTION***

Besides the refusal to fill a given prescription based upon a religious, moral or ethical belief as described above, and what must occur subsequent to that refusal, there are two other circumstances where a prescription may not be filled and what is required to be done by the pharmacist:<sup>47</sup>

- (1) If the pharmacist, based upon his or her professional training, experience, knowledge and good judgment is convinced that the dispensing of the prescription is contrary to the law, or has the potential of causing a harmful result based upon a possible drug interaction, dosing mistake, allergic reaction or some other factor that would be detrimental to the health of the patient, the pharmacist must contact the prescriber in an attempt to have the prescriber make any necessary changes. To not fill the prescription may very well result in a benefit to the patient.
- (2) If the drug is not in the pharmacy's stock, and there is otherwise no reason not to fill the prescription, then the pharmacist will be expected to:

- a. Immediately notify the patient and arrange for the drug to be delivered to the patient in a timely manner, or
- b. Promptly transfer the prescription to another pharmacy that has the drug or device and that is near enough to ensure that the patient has timely access to acquire the drug or device, or
- c. Return the prescription to the patient and refer the patient to a pharmacy that stocks the drug or device that is near enough to ensure that the patient has timely access to the drug or device.

Based upon the above, it is no longer appropriate to simply give the patient back the prescription indicating that you do not have the item in stock, or it can not be filled as written, without informing the patient about the alternatives in taking the necessary other actions noted above.

The Board of Pharmacy in 2008 amended its “*Notice to Consumers*” statement that must be posted in a conspicuous place in the pharmacy area.<sup>48</sup> The language that was added to the *Notice To Consumers* states:

*Know your rights under California. Law concerning medicine and devices prescribed for you. You have the right to receive medicine and devices legally prescribed for you, unless:*

1. *The medicine or device is not in stock in the pharmacy.*
2. *The pharmacist, based upon his or her professional judgment determines providing the item:*
  - *Is against the law.*
  - *Could cause a harmful drug interaction, or*
  - *Could have a harmful effect on your health.*

*This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy in a timely manner.*

*The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.*

*If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.*

*Any questions? Ask your pharmacist!*

### ***MAY A PRESCRIPTION BE WRITTEN AND FILLED FOR AN "OFF-LABEL" USE?***

U.S. District Court Judge Royce Lamberth ruled in July 1999 that it was unconstitutional for the Food and Drug Administration to regulate the pharmaceutical industry's ability to distribute information on "off-label" use of prescription drugs.<sup>49</sup> Prior to this ruling, the FDA posed the following requirements on the manufacturers of pharmaceutical products:

- That the pharmaceutical manufacturers would be required to submit a new application for a drug before promotion of its "off-label" use.
- That the pharmaceutical manufacturers would be required to submit promotional materials for review before distribution.
- That the pharmaceutical manufacturers would be required to submit reports semiannually on industry promotional activities.

As a result of the court decision, manufacturers of drugs, biologicals, and devices approved by the FDA would be allowed to disseminate what the FDA describes as "*sound and balanced*" information about "off-labeled" uses of these products to physicians and health plans.

California has also approved legislation to allow an existing FDA approved drug to be used “Off-Label” if the medical need involves:<sup>50</sup>

- A life threatening condition – Where there is a potential for death is high, or
- A chronic and/or disabling condition – where there is interference with one or more life activities and where the condition may persist for years.

The California law also suggests that the “off-labeled” drug use is recognized for a specific treatment in anyone or a combination of the following sources:

- AMA Drug Evaluations,
- American Hospital Formulary Service,
- USP Dispensing Information, and/or
- Articles from major peer reviewed medical journals.

There is also a provision in the state law directed to health care service plans that might otherwise disallow a drug for a patient because of its “off-labeled” use characterization.<sup>51</sup>

The new law attempts to discourage health care organizations from not using a drug for a potentially life-saving condition because of its off-labeled status.

### ***WHAT REQUIREMENTS ARE THERE FOR THE MEDI-CAL TAMPER-RESISTANT PRESCRIPTIONS?***

Effective October 1, 2007 all written prescriptions for Medi-Cal or Medicaid outpatients are required to be written on a tamper-resistant prescription blank. This requirement applies to all outpatient written prescriptions as well as prescriptions written for non-prescription drugs.<sup>52</sup> The prescription pad used for Medicaid prescriptions must contain all of the following elements, effective October 1, 2008:

- One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription;
- One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; and
- One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

While the Medicaid prescription forms do not need to meet the same California standards as the security prescription forms used for the writing of controlled substances (e.g. boxes checked-off with the number of units of medication written for), these controlled substance security forms fully meet the federal Medicaid requirements.

It was noted in the February 2009 Script published by the California State Board of Pharmacy, that “controlled substance prescriptions written on Medi-Cal prescription pads containing only the three requirements above, are in violation of Health and Safety Code, Section 11162.1, which has additional requirements.”<sup>53</sup>

The tamper-resistant form requirement does not apply to refills of written prescriptions presented at a pharmacy before October 1, 2007. In addition, the special form requirement does not apply to “E-prescriptions” transmitted to the pharmacy, prescriptions faxed to the pharmacy, or prescriptions communicated to the pharmacy by telephone by a prescriber.<sup>54</sup>

### ***MAY A PHARMACIST PLACE FALSE OR MISLEADING INFORMATION ON A PRESCRIPTION LABEL?***

A prescriber may write a prescription that causes a pharmacist to prepare a prescription label that is false, misrepresents, or covers-up the true identity of the drug substance that is dispensed to the patient under either of the following limited circumstances:<sup>55</sup>



- If the labeling is a necessary part of a clinical or investigational drug program approved by the FDA or a legitimate investigational drug project involving a drug previously approved by the FDA. As an example, where a double-blind study is in progress on an investigational drug, the prescriber may be prescribing a placebo for one set of patients chosen randomly, and an actual active drug for another set of patients. In both cases the label affixed to the drug container may state the name of the active investigational drug whether it is a placebo or not for purposes of ensuring that the study results are unbiased.
- If, in the medical judgment of the prescriber, the labeling is appropriate for the proper treatment of the patient. As an example, if a prescriber is fearful of a patient becoming addicted to a given drug and wishes the pharmacy to dispense a placebo, the patient's label affixed to the drug container may contain the name of the active drug even though the container content is a placebo. Again, this action must take into account whether or not what is done is "appropriate for the proper treatment of the patient."

#### ***MAY A PHARMACIST GIVE REBATES OR DISCOUNTS TO OTHERS FOR A REFERRAL***

Any gift or money given either as an inducement or an award for sending a customer to a pharmacy is strictly unlawful. The giving of a gift or money by a health care practitioner to a pharmacy or pharmacist in return for referring a patient is also unlawful.<sup>56</sup> However, if there is a charge for products or services wherein a profit is derived based upon a referral, if that profit is ordinary and customary to the usual sale of the product or service, whether or not a referral was made, the entitlement to the usual profit derived is not forbidden or unlawful.

As an example, if you are a pharmacy owner and you also own 50% of a medical-surgical supply business located four blocks from your pharmacy, and a patient asks you for a particular medical device whereupon you send him to the medical-surgical supply operation four blocks away to buy the item, you are not in violation of the statute. No violation occurs because the item purchased would sell for the same price to a customer whether or not the referral was made. Because of your 50% ownership, you are entitled to 50% of any profit derived from this sale. Also note that it does not matter if there are six other medical-surgical supply businesses nearer to your pharmacy than the one in which you have a 50% ownership. Furthermore, it does not matter if your medical-surgical supply operation charges more than the other six medical-surgical supply operations.

On the other hand, if you send the customer to the medical surgical supply operation and you expect a 10% rebate from your other partners for the referral, you are clearly in violation of the law.

The party making a referral to a business in which that party has a business interest should be disclosed to the consumer who is being advised of the other business.

Generally speaking, in any rebate or discount arrangement, as long as the patient is the primary beneficiary of the rebate or discount arrangement it is less likely to be challenged as an unlawful situation.<sup>57</sup>

In October of 2007 federal rules on “rebates and discounts” made a further concession regarding the free giving of hardware, software, and information technology and training by a company who might benefit by a health center entity (assumes the inclusion of pharmacy) using their products if such items contribute “to the ability of a health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.”<sup>58</sup>

**WHAT IS MEANT BY DRUG DIVERSION  
WHERE THERE IS RESALE OF  
PREFERENTIALLY PRICED DRUGS?**

Generally, a non-profit or high-volume pharmacy operation may purchase drugs from the wholesaler or the drug manufacturer at lower acquisition prices than can a small independent pharmacy that is operating for profit. As a result, the law attempts to prevent the smaller, low-volume for-profit pharmacy from purchasing its drugs from the larger high-volume, non-profit pharmacy that buys its drugs at lower acquisition costs.<sup>59</sup> The "Drug Diversion Law" (originally associated with the "Prescription Drug Marketing Act") is intended to discourage a resale of drugs by a nonprofit pharmacy to a for-profit pharmacy. If this arrangement were allowed, the for-profit pharmacy could take advantage of the nonprofit pharmacy's purchasing of drugs at greatly reduced prices without passing any of the savings onto the consumer. Thus, the law attempts to prevent the nonprofit pharmacy from acting as a wholesaler for the for-profit pharmacy.

When the "Drug Diversion Law" was first introduced, its primary purpose was to control the reselling of prescription drugs between hospital pharmacies for the reason explained above. However, the implications of preferential pricing apply to community pharmacies as well. This law also functions to: 1) keep non-profit and for-profit hospital pharmacies from competing with community pharmacies for prescription business, and 2) keep non-profit and for-profit hospital pharmacies, as well as community pharmacies, from making money by selling off their inventories, acquired at preferential prices, to other entities not eligible for those special prices.<sup>60</sup> (See 21 U.S. Codes, Sec. 353[c]-[e] for further discussion regarding this topic.)

There are, however, a few exceptions to this ruling whereupon a pharmacist may purchase a drug at a lower price from another pharmacy and sell the drug on prescription at his or her usual price. These exceptions include:

- When for the persons own use.<sup>61</sup>
- Where the lower-cost drugs are sold to a purchaser also eligible for those prices under the Nonprofit Institutions Act.<sup>62</sup>
- When sold to a walk-in customer pursuant to a prescription, provided that those sales represent less than one percent of the drugs purchased annually by the pharmacy.<sup>63</sup> This circumstance will usually occur in a non-profit hospital pharmacy who purchases its inpatient drugs at the preferentially low price and then wishes to accommodate a walk-in patient's need for a prescription drug. Keep in mind that in order for a hospital to fill prescriptions for outpatients it will generally require a second license from the Board to do so, and wholesale costs of drugs by the hospital for outpatient prescription purposes will generally cost more than for inpatient wholesale purchases, especially for a nonprofit hospital.
- If a specific drug is not readily available pursuant to the emergency prescription need of a patient, a for-profit pharmacy may borrow the drug from a non-profit pharmacy, if available, and dispense it to a patient at that for-profit pharmacy's usual and customary prescription price.<sup>64</sup> However, the borrowed drug must be returned to the non-profit pharmacy exactly as it was attained originally (same drug, strength, amount and manufacturer). Thus, there cannot be generic drug equivalents returned, or other drugs used to replace the borrowed drug from the non-profit pharmacy. Most important is that the for-profit pharmacy MAY NOT PURCHASE THE DRUG from the non-profit pharmacy.

***MAY A HOSPITAL'S EMERGENCY ROOM  
DISPENSE DRUGS?***

A prescriber may dispense a prescription drug, including a controlled substance, to an emergency room patient only if:<sup>65</sup>



- The hospital's outpatient pharmacy is closed and there is no pharmacist available in the hospital;
- The prescription drug is acquired by the hospital; and the dispensing of the drug and its amount dispensed is kept as record by the pharmacy.
- The prescriber and E.R. pharmacy staff that dispenses the drug must reasonably believe that a pharmacy outside the hospital is not available to provide the prescription drug.
- The amount of drug dispensed from the E.R. area is to be limited to that amount necessary to maintain uninterrupted therapy, and shall not exceed a 72 hour supply. The hospital pharmacy may prepackage the 72 hour supply to be placed in a Pyxis or other medication dispensing device "safe" for dispensing to an E.R. patient only when there is no pharmacist available to provide the outpatient pharmacy services.

***WHAT IS INVOLVED IN THE IMPAIRED  
PHARMACIST RECOVERY PROGRAM  
AND HOW DOES IT OPERATE?***

By definition, an impaired pharmacist (also includes pharmacist-intern) is one whose competency may be impaired due to the abuse of alcohol or drug substances, or mental illness. The purpose of the "Pharmacist Recovery Program" is to rehabilitate such pharmacists through treatment programs so that they may return to the practice of pharmacy and not pose a danger to patient public health and safety.<sup>66</sup> What constitutes an alcohol, drug or mental disease state problem is an issue of fact and must be determined on a case-by-case review basis.

To administer this Program, the Board of Pharmacy contracts with an outside agency designated as the Employee Assistance Program Agency.<sup>67</sup> The Board of Pharmacy may refer licentiates to this Agency, or those with a problem may voluntarily submit themselves to the Agency without reporting the submission to the Board.<sup>68</sup> Either way, the



Agency keeps all reports of any impaired pharmacists within the Program confidential.

Among the functions of the Employee Assistance Program are the following:<sup>69</sup>

- To evaluate pharmacists who wish to participate in the Pharmacist Recovery Program.
- To develop a treatment contract with each participant in the Recovery Program
- To monitor the compliance of each participant in the Program.
- To consider treatment facilities and services to which pharmacists in the Program may be referred.
- To prepare reports for submission to the Board of Pharmacy if required.
- To inform the participant of the procedures to be followed in the Program.
- To inform the participant of his or her rights and responsibilities while in the Program.
- To inform each participant of the possible consequences of noncompliance with the Program.

The Board contracts with a statewide pharmacists' professional association to work with the Employee Assistance Program Agency to identify, select, and train licensed pharmacists to serve as "volunteer interveners." Each impaired pharmacist involved in the Recovery Program will work under the supervision of a volunteer intervener. If at any time an impaired pharmacist in the Program is found not in compliance with the standards set forth in the Program's policies, that pharmacist will be terminated from the Recovery Program, and the Board of Pharmacy must be informed of that termination.<sup>70</sup> The Board will then determine whether that party is eligible to continue in the Program, or if disciplinary action should be taken against him or her.<sup>71</sup>

If the Recovery Assistance Program staff determines that a pharmacist is no longer impaired, that pharmacist may, upon review, return to a non-supervised status.

### ***WHAT RULES EXIST FOR PRESCRIBERS WHO ARE INVOLVED IN THE DISPENSING OF DRUGS?***

The general rules regarding the dispensing of drugs by a prescriber directly to the patient involve the following considerations:

- The drugs must be dispensed directly to the patient by the prescriber in his or her office practice.<sup>72</sup> The prescriber is responsible for counting or pouring the drug into a vial or bottle, and properly labeling that vial or bottle before dispensing it to the patient.
- The prescriber must fulfill all of the labeling requirements imposed upon the pharmacist as well as the dispensing of the drug in childproof containers and the maintaining of necessary records.<sup>73</sup>
- A nurse practitioner, physician assistant, or a certified nurse midwife pursuant to a prescriber initiated protocol may hand to a patient of the supervising prescriber a properly labeled prescription drug appropriately prepackaged by the prescriber, manufacturer, or a pharmacist.<sup>74</sup> The prescriber may dispense samples to the patient without the usual labeling if such samples are: a) in packages prepared by the manufacturer, and b) not paid for by the patient or any health care program to which the patient belongs.<sup>75</sup> An appropriate record of provided sample medications is to be entered into the patient's chart.<sup>76</sup> A nurse practitioner, physician assistant, certified nurse midwife or naturopathic doctor pursuant to a supervising prescriber's protocol may now also furnish samples properly packaged by the manufacturer to patients.<sup>77</sup> The NPs, PAs, CNMs or NDs pursuant to a supervising prescriber's protocol can also sign for the delivery or receipt of complimentary samples that have been requested in writing by the prescriber.<sup>78</sup>
- If the prescriber is to dispense drugs to the patient, a written disclosure must be made available to the patient indicating that the patient has a choice to obtain the

drug(s) either from the prescriber or from a pharmacy of the patient's choice.<sup>79</sup>

The California Medical Board, Osteopathic Medical Board, Dental Board, Veterinary Medical Board, Nursing Board, Optometry Board, Physician Assistant Committee as well as the California Board of Pharmacy, are responsible for the enforcement of the above rules as it pertains to practitioners licensed by their respective agencies.<sup>80</sup>

***WHAT DOES THE BOARD OF PHARMACY  
CONSIDER TO BE ACTS OF UNPROFESSIONAL  
CONDUCT WHEREBY IT MAY TAKE ACTION AGAINST A  
PHARMACIST'S LICENSE?***

Unprofessional conduct shall include, but is not limited to:<sup>81</sup>

- Violation or attempted violation of the law (federal or state), especially law pertinent to the practice of pharmacy.
- Assisting in or abetting the violation of or conspiring to violate any law, especially pertinent to the practice of pharmacy.
- Acts of gross immorality.
- Incompetence.
- The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption.
- Gross negligence.
- The clearly excessive furnishing of controlled substances whereby such substances are:
  - Issued without a prescription, or
  - Issued on a prescription, but not issued in the usual course of professional treatment, or
  - Issued on a prescription with the pharmacist's knowledge that the drug will be used to treat a habit or addiction and is neither a part of any authorized methadone maintenance program, nor is for any other legitimate medical purpose.

- Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
- The self administration of any prescription drug in a manner that is dangerous to oneself or to others, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.
- The conviction of more than one misdemeanor or any felony involving the use of any dangerous drug or alcoholic beverage.
- The conviction of a crime substantially related to the qualifications, functions, and duties of a licensed pharmacist.
- Engaging in any conduct that subverts or attempts to subvert an investigation by the board.
- Inappropriate exercise of one's education, training and experience as a pharmacist.
- Inappropriate exercise of the pharmacist's best professional judgment or responsibility in the dispensing of controlled substances, dangerous drugs or devices, or provision of pharmacy-related services.
- Failure to consult with patient or prescription records on a prescription drug issue.
- Failure to fully maintain and retain appropriate patient specific information pertaining to performance of any pharmacy-related function.

***A PHARMACY ETHICS COURSE MAY BE REQUIRED  
AS A CONDITION OF PROBATION***

The Board of Pharmacy, based upon the nature of a pharmacy-related violation, may require that a pharmacist not only be placed on probation, but be required to take a pharmacy-related ethics course. The Board must approve of the ethics course before the pharmacist on probation registers to take the course.

For the Board to approve the course, it must satisfy the minimal standards noted below:<sup>82</sup>

- **Duration:** The course must consist of a minimum of **22 hours**, of which at least 14 hours are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.
- **Faculty:** Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.
- **Educational Objectives:** There is a clear statement of educational objectives that can be realistically accomplished within the framework of the course.
- **Methods of Instruction:** The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.
- **Content:** The course shall contain the following components:
  - A background assessment to familiarize the provider and instructors with the factors that led to the candidate's referral to the class.
  - An assessment of the candidates knowledge and awareness of ethical and legal issues related to the practice of pharmacy in California with emphasis on areas that the candidate was found to violate.
  - An assessment of the participant's expectations of the program with their commitment to desire to change to be in compliance with ethical standards and the law.
  - Didactic presentation of material related to those areas that were problems for the participant based upon the results of the background assessments.
  - Experiential exercises that allow the participant to practice concepts and newly developed skills



they have learned during the didactic portion of the class.

- The course provider shall conduct a longitudinal follow-up that includes: 1) a minimum of two contacts at spaced intervals (e.g. 6 months and 12 months) within one year after course is completed or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and 2) a status report submitted to the Board or its designee within 10 calendar days after the last contact.
- Class Size: Shall not exceed 12 participants.
- Evaluation: The course shall include an evaluation method that documents that educational objectives have been met.
- Records: The course provider shall maintain all records pertaining to the program, including a record of attendance for each participant, for a minimum of 3 years. Such records are to be made available for inspection and copying by the Board or its designee.
- Course Completion: The provider shall issue a certificate of completion to those participants who successfully complete the program. The provider shall also notify the Board in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating lack of insight. This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

***CAN A PHARMACY-RELATED DISCIPLINARY  
ACTION IN ANOTHER STATE CAUSE  
THIS STATE TO TAKE DISCIPLINARY ACTION?***

Any disciplinary action taken by another state involving the revocation of, suspension of, or other discipline pertaining to a license to practice pharmacy, shall constitute grounds for disciplinary action in this state.<sup>83</sup>

***MUST CHILD RESISTANT CONTAINERS  
BE PROVIDED FOR EACH DRUG  
DISPENSED ON A PRESCRIPTION?***

The Consumer Product Safety Commission, in compliance with the Poison Prevention Packaging Act of 1970 requires that all oral prescription drugs, with some exceptions, be dispensed in a safety, "child resistant" container.<sup>84</sup> Prescription drugs that are for external use should, whenever possible, be placed in child resistant containers. However, prescriptions for topical application or for other non-oral administration are not required to be dispensed in child resistant containers. The Consumer Protection Agency also does not require nitroglycerin tablet products to be in child resistant containers.

A patient can request that his or her medication be issued in a non-complying container. The law does not require that such a request be furnished in writing or signed by the patient. However, it is highly recommended that written documentation exist if the patient opts to waive the receipt of his or her prescription in a child resistant safety container.<sup>85</sup>

***IS A FULL-TIME PHARMACIST REQUIRED  
IN HOSPITALS OF 100 OR FEWER BEDS?***

A hospital, whether for profit or nonprofit, with 100 or fewer beds is not required to employ a full-time registered

pharmacist, but must be licensed by the Board of Pharmacy. The purchase, storage, and provision of drugs by such a hospital may be done under the direction of a physician. Records of drugs purchased and administered by these facilities must be accurately kept.<sup>86</sup> Such records should be kept for at least a 3 year period.<sup>87</sup>

Because of the regulations and standards that must be met by a hospital in order to maintain its accreditation, with strict compliance requirements that must be adhered to by the pharmacy department, it is rare to find a hospital of 100 or fewer beds without a full-time pharmacist. At a minimum, the California Code of Regulations requires that any hospital of 100 beds or less must employ a consultant pharmacist. If a consultant pharmacist is employed by the hospital, that consultant is usually responsible for providing a written report to the Board of Pharmacy on a quarterly basis identifying any problems associated with drug ordering, storage, dispensing, recordkeeping, disposal, etc. and recommendation steps to be taken to correct those problems.<sup>88</sup> The California Department of Public Health, the agency that inspects hospitals, usually recommends that a hospital employ a full time pharmacist, especially if the nature of the care provided at that hospital necessitates unusually high drug use.<sup>89</sup>

#### ***PURCHASE OF DRUGS AT WHOLESALE BY HOSPITALS CONTAINING 100 BEDS OR LESS***

A licensed hospital of 100 beds or less may provide drugs that it purchases at wholesale for both administration, as well as dispensing pursuant to a prescriber's order. Thus, besides the inpatient administration of such drugs, the prescriber may have prescription drugs within this 100 bed or less facility that may not employ a full-time pharmacist, dispensed under the following conditions:<sup>90</sup>

- For inpatients who are being discharged.
- For emergency cases under treatment in the hospital.

- For dispensing directly by a physician to outpatients as long as:<sup>91</sup>
  - The physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued.
  - The physician reasonably believes that no other pharmacy is available and accessible to the patient within 30 minutes or a 30-mile radius of the hospital. This especially applies to hospitals in rural areas.<sup>92</sup>
  - The physician provides **no more than a 72 hour supply of the drug.**
  - The medication dispensed to the patient is properly labeled and dispensed directly by the prescriber. (See section on *“What Rules Exist For Prescribers Who Are Involved In The Dispensing Of Drugs”* within this Chapter.)

### ***ARE PHARMACISTS PERMITTED TO PERFORM CLINICAL LABORATORY TESTS?***

A pharmacist may “perform clinical laboratory tests or examinations classified as ‘waived’ or of ‘moderate complexity’ as part of the care provided by a health facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care service plan.” Such lab tests may also include tests where the results will be used for patient education or to demonstrate the use of a device for the patient.<sup>93</sup> Thus, the pharmacist may perform those laboratory tests (as skin tests) that the patient could otherwise do for themselves in the course of a routine patient assessment procedure.

As noted in Chapter 3, laboratory testing by the pharmacist appears to be dependent upon training and the type of site where this procedure is performed. In the performance of doing skin tests, the pharmacist shall report the results obtained from a test to the patient and any physician designated by the patient.<sup>94</sup>

***MAY A PHARMACIST TEMPORARILY LEAVE THE PHARMACY AREA FOR A MEAL BREAK OR OTHER BREAKS WHILE THE PHARMACY REMAINS OPEN?***

A pharmacist may leave the area of the pharmacy operation on a temporary basis for regular scheduled breaks, bathroom breaks, and meal periods without closing the pharmacy if the following conditions are met:<sup>95</sup>

- The pharmacist must reasonably believe that the security of the dangerous drugs and devices contained within will be maintained in his or her absence. If the pharmacist reasonably believes for security purposes that the pharmacy should be closed during his or her absence, then the pharmacist has the right to close the pharmacy and remove all ancillary staff during his or her absence.
- That during the pharmacist's temporary absence no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill medication that the pharmacist has checked, approved for release to the patient, and did not require a patient consultation by the pharmacist.
- That during the pharmacist's temporary absence the ancillary staff may continue to perform the non-discretionary duties authorized to them by pharmacy law. Any such duty performed during the pharmacist's absence by the ancillary staff shall be reviewed by the pharmacist upon his or her return to the pharmacy.
- That during the pharmacist's temporary absence an intern pharmacist shall be considered ancillary staff, and may not perform any discretionary duties that he or she would otherwise perform as an intern pharmacist.
- The temporary absence of the pharmacist from the pharmacy shall be limited to 30 minutes for any meal, and the pharmacist who is on break shall not be required to remain in the pharmacy area during his or her break.

The pharmacy shall have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist. Also, the policy



shall outline the duties of the ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff, and the pharmacist's responsibility for maintaining the security of the pharmacy area during the periods of absence.

### ***MAY A PHARMACIST PROVIDE PRESCRIPTION DRUGS TO OFFICERS OF AN OCEAN VESSEL?***

A pharmacy may furnish prescription drugs to the master or first officer of an ocean vessel pursuant to a written prescription.<sup>96</sup> In order for such furnishing to occur the following must take place:<sup>97</sup>

- The prescription drugs shall be ordered on the ocean vessel's official stationary and signed by the first officer.
- The drugs shall be maintained on the vessel and dispensed from medicine chests, first aid packets, or the dispensary pursuant to a standardized procedure established by a registered medical officer.
- Drugs shall be furnished in a sealed container to the ship's first officer, or delivered directly on board.
- The pharmacy shall give notice to the Board of Pharmacy **within 30 days** of undertaking this activity.
- Distribution of controlled substances shall be in accordance with the federal requirements.

### ***IS THERE A SPECIFIC PROCEDURE IN CONTESTING AN ISSUED CITATION BY A BOARD INSPECTOR?***

If a pharmacist or a pharmacy is issued a citation by a pharmacy board inspector, the pharmacist or pharmacy may contest any or all aspects of the citation in either of the following ways:

- By appealing to the board in writing **within 30 days of the issuance of the citation,**<sup>98</sup> or
- By submitting to the board in writing **within 14 calendar days after service of a citation** a request for an office

**conference.**<sup>99</sup> The office conference will be conducted by the executive officer, a supervising inspector or board member(s).

- The cited party may have legal counsel representation or an authorized representative if desired at the informal office hearing.<sup>100</sup>
- At the conclusion of the office conference, the person(s) hearing the cited party's' or entity's' testimony may affirm, modify or dismiss the citation.<sup>101</sup>
- The office conference decision and findings will be sent in writing to the cited party or entity within 14 days of the conference and shall state the reasons for their action.<sup>102</sup>
- If the findings and decision are unfavorable to the cited party or entity, then a formal hearing before an administrative law judge may be requested by the Board, in writing as a new citation, within 30 days of the issuance of the office conference decision.<sup>103</sup>

#### ***WHAT HAPPENS IF A CITED PARTY BY THE BOARD IS UNABLE TO COMPLY WITH AN ORDER OF ABATEMENT?***

“If a cited person or entity who has been issued an ‘Order of Abatement’ is unable to complete a request for a correction by the Board within the time set forth in the citation because of conditions beyond his/her or its control after the exercise of reasonable diligence, the person or entity cited may request an extension of time in which to complete the correction from the Board. Such a request shall be in writing and shall be made within the time set forth for abatement.”<sup>104</sup> Keep in mind that an “Order of Abatement” is a request (by means of a citation) that something be taken care of or be corrected, such as placing a sink in the pharmacy with hot and cold running water, if a sink happens not to be there or is not working properly. The Board will in cases where corrections can be made within a

reasonable period of time simply issue an “Order of Abatement.” If not corrected within a reasonable period of time, a “citation” requiring a fine and/or other sanctions can next be issued by the Board.

***MUST PHARMACY MANAGEMENT REPORT TO THE BOARD OF PHARMACY ANY LICENSED EMPLOYEE THEFT OR IMPAIRMENT MATTERS?***

A pharmacy will be required to have a policy and procedures outlining what steps are to be taken to protect the public when a licensed employee of the pharmacy is found to be chemically, mentally, or physically impaired sufficient to impact his or her ability to practice pharmacy in accordance with the federal and state laws, and/or practice allowances set forth under the practitioner’s license.<sup>105</sup>

It will be the responsibility of the pharmacist-in-charge or a responsible licensed employee of the pharmacy to report to the Board of Pharmacy within 14 days of having knowledge of any licensed employee where there is:<sup>106</sup>

- Any admission by a licensee of chemical, mental, or physical impairment affecting his or her ability to practice.
- Any admission by a licensee of theft, diversion, or self-use of dangerous drugs.
- Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensee to the extent it affects his or her ability to practice.
- Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensee.
- Any termination of a licensee based on theft, diversion, or self-use of dangerous drugs.

The required report to be sent to the Board of Pharmacy within 14 days shall include the following information in detail:<sup>107</sup>

- An estimate of the type and quantity of all dangerous drugs involved.

- The timeframe over which the losses are suspected.
- The date of the last controlled substances inventory.

The party creating the report to the Board is granted immunity from any liability, civil or criminal.<sup>108</sup>

***WHAT IF A PHARMACIST FORGETS TO  
RENEW HIS OR HER LICENSE AND WHAT SITUATIONS  
MAY PREVENT A LICENSE FROM BEING RENEWED***

The pharmacist license must be renewed upon receipt of the every two year renewal request sent by the Board. If the pharmacist license is not renewed within three years following its expiration it may not be renewed and canceled by operation of the law at the end of the three year period.<sup>109</sup> The consequence of this failure to renew during the three year period would require that the delinquent party retake the Board examination and pass in order for reinstatement. To have an expired license also places the working licensee in a position of practicing without a license, and subject to further disciplinary action.

Several laws have also been passed whereby the Board may not renew a pharmacy license if an otherwise registered pharmacist is not making court ordered child support payments or has defaulted on a government issued student loan.<sup>110</sup> Of recent, defaults on owed payments to the California Board of Equalization will also interfere with the renewal of one's license. Renewal will only be considered if the licensee makes good on his or her defaulted child support, government loan payments, or other deficient tax payments due or provides evidence of a satisfactory repayment arrangement.

***IS IT REQUIRED THAT A PHARMACIST MUST  
REPORT THE AMOUNT OF A MONEY SETTLEMENT  
PAID BY THE PHARMACIST IN A  
PHARMACY-RELATED LAWSUIT?***

Settlements or arbitration awards in a civil lawsuit are usually not public knowledge as compared to a civil case that goes to the courts whereupon a judgment is rendered by either a judge or jury. Therefore, settlements or arbitration awards where the pharmacist must pay-out \$3,000 or more as the result of a pharmacy-related matter, must be reported by either the pharmacist or the licensed pharmacist's insurer to the Board within 30 days after the settlement or arbitration award is finalized and provided to all the parties.<sup>111</sup> The report to the Board must be signed by each of the parties to the action.

***MAY PRESCRIPTIONS BE SENT FROM  
A PRESCRIBER'S OFFICE TO A PHARMACY  
USING THE INTERNET?***

The law does not disallow prescriptions for dangerous drugs or devices from being transmitted from a prescriber over the Internet to a pharmacy. However, any prescription transmitted in this manner must be pursuant to a good faith and appropriate examination. Therefore, it is the responsibility of the receiving pharmacy to ensure both the authenticity of the prescription and that a good faith examination (or an "appropriate prior examination") was conducted by the prescriber.<sup>112</sup> It appears that the basis of a "good faith examination" (or an "appropriate prior examination") should include:

- The existence of a prescriber-patient relationship.
- Medical records kept by the prescriber on the medical or veterinary care of the patient.
- A physical examination or at least a line of questioning by the prescriber to ascertain the nature of the medical problem.



Under the Ryan-Haight Online Pharmacy Consumer Protection Act of 2008 any person who plans to operate an “online pharmacy” must obtain DEA registration allowing the pharmacy to be identified as an online pharmacy. Accordingly, the pharmacy will be responsible for reporting monthly to the DEA the dispensing of 100 or more controlled substance prescriptions or 5,000 or more dosage units of such drugs.<sup>113</sup>

If there is a violation of the requirement for Internet transmission of a prescription, the pharmacy or pharmacist may be subjected to a fine of up to \$25,000 per occurrence.<sup>114</sup>

In regards to the prescribing of controlled substances over the internet, Chapter 14 covers specific requirements under the rules for “E-prescribing.”

***CANDIDATES SITTING FOR THE CALIFORNIA  
BOARD EXAM ARE HELD TO OBSERVE STANDARD  
REQUIREMENTS IN NOT PASSING INFORMATION  
REGARDING THE EXAM TO OTHERS***

It is extremely important that each candidate and those who are licensed by the California Board of Pharmacy do not breach any of the ethical or legal standards associated with the California Board of Pharmacy licensure examination.

Section 123 of the CA Bus. & Prof. Codes states in pertinent part, “It is a misdemeanor for any person to engage in any conduct which subverts or attempts to subvert any licensing examination or the administration of an examination... Such subversion shall include:<sup>115</sup>

- The unauthorized reproduction of any portion of the actual licensing examination.
- Paying or using professional or paid examination takers for purposes of reconstructing any portion of the examination.
- Using or purporting to use any examination questions or materials which were improperly removed or taken from any examination.

- Using or purporting to use any examination questions or materials which were improperly removed or taken from any examination for purposes of instructing or preparing any applicant for an examination; and
- Obtaining questions or other examination materials, except by specific authorization either before, during or after an examination.”

Section 1723.1 of the California Business and Professions Codes states, “Any applicant for any license issued by the Board who removes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license.”<sup>116</sup>

In addition, a pharmacist candidate taking the California Board Examination who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for three years from the date of the incident, and shall surrender his or her intern license until eligible to take the examination. The candidate may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.<sup>117</sup>

***SHOULD A PHARMACIST FILL A PRESCRIPTION FOR A CELEBRITY USING A FICTITIOUS NAME ENTERED ON THE PRESCRIPTION BY THE PRESCRIBER?***

While it is understandable that celebrities have a right to privacy, especially when they are brought to a hospital or come into a community pharmacy to fill a prescription, the law about prescribers writing fictitious names on the prescriptions issued to celebrities and filling prescriptions using those fictitious names is not supported by California statutes. In regards to controlled substances, one statute states, “No person shall, in connection with the prescribing, furnishing, administering, or dispensing of a controlled substance, give a false name or false address.”<sup>118</sup>

The rule for controlled substances would appear to apply to non-controlled substance prescriptions as well since another statute in the California Business and Professions Codes states that the name of the patient must appear on the prescription.<sup>119</sup> This would suggest that the real name of the patient will need to be transcribed onto the prescription.

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## CHAPTER 5

# THE LAWS REGARDING PATIENT CONFIDENTIALITY AND QUALITY ASSURANCE PROGRAMS

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## ***PATIENT HEALTH INFORMATION CONFIDENTIALITY***

Patient health information confidentiality has been a growing area of concern over the last several years, and will continue to be a topic of ongoing issues. Because of patient and government interest in this area, it seemed appropriate to construct a chapter that would hopefully provide insight on this subject and answer some of the common questions that a pharmacist might have pertaining to the patient's rights regarding confidentiality of their health care information. Please keep in mind that the area of rules and regulations regarding a patient's health care information is an ongoing process, and as new methods of transmitting, handling, storing, or sharing this information become available, new rules and regulations will more than likely have to be established.

### ***A. Background Regarding The Confidentiality Of Patient Care Information***

The state laws have provided, and continue to provide, important rulings on how patient care information is to be protected. In California the following Acts or regulations set forth strict rules on patient care information:

- *Confidentiality of Medical Information Act (CMA)*
- *Patient Access To Medical Records Act (PAMRA)*
- *Medical Calif. Family Codes and Regulations - (Protects the sharing of medical information among members of the family, especially as it relates to children.)*
- *Lanterman-Petris-Short Act (LPSA) – (Information related to the care and treatment of mentally ill patients.)*
- *Title 16, Calif. Code of Regulations, Section 1764 – ( The pharmacists duty in maintaining patient care information confidential)*

The law that is presently dominating the patient care information protection scene is the federal law entitled,



*Health Insurance Portability and Accountability Act*, commonly referred to as “*HIPAA*.” Because of the importance of this law, a good portion of this chapter will be devoted to a general discussion on what HIPAA covers and how it will most likely affect the practice of pharmacy both nationally and in California.

*B. How Do The California Statutes And Regulations Address The Maintaining Of Confidentiality Of Patient Care Information By The Pharmacist?*

The California laws hold the pharmacist to maintaining a strict level of confidentiality and privacy concerning information about prescription medications a patient is receiving, the patient's medical status or experienced illnesses, and any other information of a medical nature conveyed in confidence to the pharmacist either by the patient, a representative of the patient, or those medical personnel involved in the patient's treatment and care.<sup>1</sup> Parties usually privy to the medication or medical information known to the pharmacist are: 1) the patient him- or herself, 2) the patient's authorized representatives who have the permission of the patient to receive such information, 3) the prescriber or other licensed health care practitioners caring for the patient, 4) another licensed pharmacist serving the patient, or 5) a person authorized under the law to receive such information (e.g. pharmacy board inspectors conducting a criminal or administrative investigation).<sup>2</sup>

For insurance companies or attorneys to have access to a patient's pharmacy records the patient generally must either provide written consent or a subpoena for such records to be issued. As a general rule there must be consent from the patient for the release of medical information.

The Calif. Civil Codes have attempted to carve out exceptions that will allow those that hold custody over medical information to release such information without consent from the patient given the following circumstances:<sup>3</sup>

- A court order request, including a subpoena for the records.
- A request by the Board of Pharmacy, a commission, or an administrative agency.
- A request from an arbitrator whereby the records are an issue to be placed in evidence at an arbitration hearing.
- A request through a search warrant issued by a law enforcement agency.
- A request from a coroner in the course of an investigation.

Also, a provider of health care, or a health care service plan may disclose medical information as follows:<sup>4</sup>

- To other health care plans, to providers, or other health care contracted services for purposes of diagnosis or treatment of the patient.
- To an insurer, employer, health care service plan, employee benefit plan, government authority, etc. if such groups are responsible for paying for the patient's health care.
- To those who provide billing, claims management, and medical data processors.
- To independent medical review organizations who review competence or qualifications of health care professionals and health care plans as to the effectiveness of the service, quality of care, or charge justification.
- To licensing agencies.
- To health care plans having a network system with other health care plans under a contractual arrangement.

The immediate set of exceptions above are for the most part contained in the federal HIPAA regulations. The HIPAA regulations attempt to provide more detail and insight on how the exceptions operate. In addition, the

HIPAA regulations direct attention to such matters as what constitutes patient consent, what are considered incidental uses and disclosures of patient information, the health care provider's sharing patient information with business associates, following the "minimum necessary" standard of providing patient information, and what constitutes proper notice to a patient as to the type of information that can be made available and to whom are some of the many issues addressed under the Act.

*C. The Health Insurance Portability And  
Accountability ACT (HIPAA)*

HIPAA as described above, provides both depth and dimension as to what is expected of health care providers and the organizations they work for regarding the handling and sharing of patient care information. One of the major intents of the Act when it was introduced in 1996 was to allow patients to switch health plans when they moved from one employer to another without being denied health insurance coverage. A portion of the Act directs attention to dealing with the electronic transfer of patient information and the concern of having in place safeguards that secure and protect the privacy of that information. The Department of Health and Human Services was charged by Congress to establish regulations for the necessary privacy safeguards to be in effect by April 1, 2001, with a two year allowance (by April 1, 2003) to make any appropriate modifications. Therefore, all responsible entities subjected to the HIPAA regulations had two years to comply with the final rule's provisions and prepare policy and procedures that correspond to the requirements of the regulations. An additional year was afforded to smaller health care plans to comply).

Essentially, providers and health plans will be required to give patients a clear written statement on how the provider or health plan may use and disclose the patient's health care information.<sup>5</sup> While the written

statement would appear to be a consent form, the recipient of the health care services need only acknowledge receipt of the written notice statement provided. Upon the patient's receipt of this notice the patient should be asked to acknowledge such receipt by his or her signature on a form that must be kept in the pharmacy for at least six years. If the patient receives the notice, and does not sign, the pharmacist can essentially sign for the patient indicating that the patient was provided with the notice.

The HIPAA written notice provided to the patient shall cover the three areas where information about the patient's health care may be directed without securing future approval from the patient:<sup>6</sup>

- *Treatment (T)*— generally means the provision, coordination, or management of health care and related services among health care providers or by a health care provider with a third party, consultation between health care providers regarding a patient, or the referral of a patient from one health care provider to another.
- *Payment (P)*— encompasses the various activities of health care providers to obtain payment or be reimbursed for their services.
- *Health Care Operations (O)* – are certain administrative, financial, legal, and quality improvement activities of a covered entity that are necessary to run its business and to support the core functions of treatment and payment.

While the above areas (*TPO*) are covered within the written notice to the patient, and is referred to as the "consent" document, the term "authorization" under the HIPAA Privacy Rule means something different. "By contrast, an 'authorization' is required by the Privacy Rule for uses and disclosures of protected health information not otherwise allowed by the Rule."<sup>7</sup> As an example, assume a patient does not want information about the antidepressant drugs her doctor prescribed for her to be disclosed to the third party payer or to any other entity outside the pharmacy that serves her prescription needs since she will pay for them out of her own pocket. To protect the patient's

request for information that could otherwise be disclosed, the patient will need to sign an authorization that should state the information the patient wishes protected and the entities that are not to receive it.

Discussed below are some of the major issues addressed by the regulations that apply both universally and specifically to the practice of pharmacy.

**1. What is required of the health care provider or the patient's health plan?**

At a minimum the health care provider and/or the patient's health plan is required to do the following:<sup>8</sup>

- Notify the patient about their privacy rights and how their health care information can be used.
- Adopt and implement privacy policies and procedures to be used at the patient practice site.
- Provide training for health care employees so that they understand the privacy policies and procedures implemented.
- Designate an individual who will be responsible to ensure that the privacy policy and procedures are implemented, followed, and updated.
- Ensure that patient records are secure and not readily available to those who have not purpose to review them.

**2. Who are the "Covered Entities" under HIPAA's Privacy Rule?**

- Health plans
- Health Care Providers
- Health care clearinghouses – a source that translates a claim from a non-standard format into a standard transaction on behalf of a health care provider and forwards the processed transaction to a payer.
- Business Associates<sup>9</sup> – a person or organization that performs a function or activity, usually under a contract, on behalf of a covered entity, but is not part of the covered entity's workforce. A member of the covered entity's workforce is not a business associate.



3. What information must be on the written Notice provided to the patient?

The Notice to the patient must describe how medical information about the patient may be used and disclosed and how the patient can get access to this information. The following should be considered in constructing the Notice statement:<sup>10</sup>

- Disclosures and uses for TPO information.
- Privacy rights (protections, accessibility to own information, making corrections or amending one's record, and accounting disclosures).
- Disclosures without individual authorization.
- Descriptions and examples.
- Statement that any other disclosures will require individual authorization.
- Procedures in filing complaints.

4. Must a patient sign a consent form or provide verbal consent to allow his or her health care information to be sent to the various covered entities described above?

The consent requirement has been eliminated from the HIPAA Privacy Rule. As noted in a publication by the Office of Civil Rights:<sup>11</sup>

*"The consent requirement created the unintended effect of preventing health care providers from providing timely, quality health care to individuals in a variety of circumstances. The major problem was that health care providers would not be able to use or disclose protected health information for treatment, payment, or health care operations purposes..., which is routinely done to provide timely access to quality health care."*

A problem that would exist for pharmacists if consent was required would be that they would not be able to fill a prescription, search for potential drug interactions, determine eligibility, or verify coverage before the patient arrived at the pharmacy to pick up the prescription unless

the patient had already provided prior consent to do so. While consent is not required, the patient must still receive notice of how his or her patient health care information will be used or disclosed. A patient still has the right to request restrictions on the use or disclosure of his or her health information as provided by the Privacy Rule.

5. *Can health providers engage in confidential discussions with other health care providers or patients even though there is a chance of the conversation being overheard?*

It is recognized that conversations regarding a patient between individuals associated with the covered entities or between patients and health care providers is generally necessary in order to provide quick, effective, and high quality health care. These conversations can on occasion be unavoidably overheard. The Privacy Rule takes these incidental disclosures into account and only expects that there be reasonable provisions made to minimize a patient's health care information from being overheard. Therefore, under the rule, it is reasonable that a pharmacist discuss a prescription with a patient over the pharmacy counter, or with a physician or the patient over the phone, but do so in a manner that there is a minimal chance of incidental disclosure to others who may be nearby.<sup>12</sup>

6. *What is meant by the "Minimum Necessary" standard?*

Covered entities must implement reasonable minimum necessary policies and procedures that limit how much protected health information is used, disclosed, and requested for certain purposes. Also, employees in the organization may have limited health care roles, and should therefore only have that degree of health care information that is minimally necessary to perform their job responsibilities.<sup>13</sup>

7. *May a pharmacist leave a message about a patient's prescription information at the patient's home on either the phone answering machine or with a family member?*

The HIPAA Privacy Rule does allow the pharmacist to leave messages about the patient's prescription medications either on a phone answering machine or with a

family member or someone at the home who is not a family member. The communication may also include a mailed notice to the home reminding the patient of a prescription refill. It is important to note that the communication should provide what is minimally necessary in the way of information.<sup>14</sup>

8. *Does the HIPAA Privacy Rule protect a minor's right to keep his or her prescription information confidential in respect to a parent's inquiry about the child's medication history?*

The HIPAA Privacy Rule defers the rights of minors in regards to their parents or guardians inquiring about their child's medical treatment to state law. In California, as a general rule, a minor's prescription records are protected as the minor's own private information, and may only be released pending the minor's consent.<sup>15</sup> Confidentiality may dissipate for a minor if the minor is under 15 years of age and the parents are paying for the child's medical care and prescriptions.<sup>16</sup>

9. *Under the HIPAA Privacy Rules what is the role of the "Business Associate" in relationship to the health care provider?*

Usually the services of business associates are contracted for by the covered entity in order to carry out the covered entity's health care functions. Within the contract relationship are built-in assurances that the business associate will safeguard all information it receives from the health care provider or health plan from misuse, and will only use information it receives to serve the needs of the health plan or health care provider.<sup>17</sup> In pharmacy, a major business associate might be a pharmacy benefits manager contracted with to manage a health plan's pharmacist network.<sup>18</sup>

**10. May a patient have a friend or family member pick up a prescription for him or her?**

“Yes. A pharmacist may use professional judgment and experience with common practice to make reasonable inferences of the patient’s best interest in allowing a person, other than the patient, to pick up a prescription.<sup>19</sup> For example, the fact that a relative or friend arrives at a pharmacy and asks to pick up a specific prescription for an individual effectively verifies that he or she is involved in the individual’s care, and the HIPAA Privacy Rule allows the pharmacist to give the filled prescription to the relative or friend. The individual does not need to provide the pharmacist with the names of such persons in advance.”<sup>20</sup>

***MEDICATION ERRORS: QUALITY  
ASSURANCE PROGRAM***

Every pharmacy by January 2002 was required to establish a quality assurance program that, at a minimum, documents medication errors attributable, in whole or in part, to that pharmacy or its personnel.<sup>21</sup> The purpose of such a program is to assess why errors are occurring, maintain records of such errors, and to take the necessary steps to help eliminate or reduce the occurrence of future medication errors.

The medication error records are not subject to discovery in arbitration, civil actions, or other proceedings, except that the Board of Pharmacy may review such records as necessary to protect the public health and safety.<sup>22</sup>

The state regulation outlines both the purpose and the process that must be followed in order to be in full compliance with the requirements of the Medication Error Quality Assurance Program:

- The pharmacy shall document and assess medication errors in order to improve the quality of pharmacy services and prevent errors.<sup>23</sup>
- “Medication Error” means any variation from a prescription or drug order not authorized by a



prescriber. This shall not include any variation that is corrected prior to furnishing the drug to the patient.<sup>24</sup> It should also be noted that if there is a significant or unreasonable delay in the patient receiving his or her prescription, this can be construed as a medication error.

- There must be written policies and procedures outlining the pharmacy's quality assurance program.<sup>25</sup>
- Unless the pharmacist has already been notified by the prescriber or the patient regarding a medication error, the pharmacist shall immediately communicate to the patient and the prescriber the fact that a medication error has occurred and the steps taken to avoid injury or mitigate the error.<sup>26</sup>
- The pharmacy shall use the findings of its Quality Assurance Program to develop pharmacy systems and workflow processes designed to prevent subsequent medication errors.<sup>27</sup>
- An investigation of each medication error shall commence at least no later than 2 business days from the date the error was discovered. The identified medication error will be subject to a quality assurance review to determine system or process failures.<sup>28</sup>
- The Quality Assurance Report to be written up shall contain at least:<sup>29</sup>
  - The date, location, and participants in the Quality Assurance review;
  - The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact;
  - The findings and determinations generated by the Quality Assurance review; and
  - Recommended changes to pharmacy policy, procedures, systems, or processes, if any.
- The pharmacy personnel shall be informed of all changes to policy, procedures, systems, or processes as a result of recommendations generated by the Quality Assurance Program.<sup>30</sup>



- The Quality Assurance record for a given situation shall be stored and immediately retrievable in the pharmacy for one year from the date the record was created.<sup>31</sup>
- A pharmacy may contract or arrange for the provision of personnel or other resources with a third party having the necessary skills or expertise to aid in satisfying the requirements of Quality Assurance regulation.<sup>32</sup>

Generally when a medication error occurs, and once it has been discovered, the pharmacy after making the necessary corrections in the error should write-up an "Incident Report" that describes the incident in detail, the parties involved, and what was done by the pharmacy. While this Incident Report has much of the same information that a Quality Assurance Report would have, there are major differences in the two reports:

- The Incident Report is prepared to be given to the pharmacy's insurance company. The Quality Assurance Report is not provided to the insurance company and is maintained at the pharmacy.
- The Incident Report is an accounting of when and what occurred and the parties involved. The Quality Assurance Report gives not only an accounting of when and what occurred, but what was learned and done about the error in order to prevent future similar errors.
- The Incident Report must state the names of parties involved in the medication incident. The Quality Assurance Report does not have to state the names of the people involved in the medication error incident, only their employment classification (e.g. pharmacist, pharmacist intern, pharmacy technician, or clerk).
- The Incident Report is discoverable in arbitration, civil actions, or other proceedings. The Quality Assurance Report is not discoverable.

As noted above, every pharmacy must have a policy and procedure in place describing its Medication Error Quality Assurance Program along with a Medication Error Review Form. Provided below is a general sample of how such a

Medication Error Quality Assurance Policy and Procedure, and Medication Error Review Form might appear for use within a pharmacy.

### ***POLICY & PROCEDURE FOR Q.A. PROGRAM EXAMPLE***

#### **Policy:**

As of January 14, 2002 this pharmacy has instituted a Quality Assurance Program that will operate to reduce the number of medication errors that may occur.

#### **Procedure:**

(1) Immediately after being aware of a medication error, the pharmacist involved shall with due diligence contact the patient and prescriber and notify them of the error and the steps being taken to avoid injury or mitigate the error. This need not be done if both the patient and prescriber are already aware of the error.

(2) An investigation of the medication error shall commence within 48 hours of it being discovered and shall be subjected to a quality assurance review

(3) Upon the occurrence of a medication error, the PIC or a designated pharmacist shall fill-out the attached "Medication Record Review Form" within 48 hours of the medication incident. This form shall be kept in the pharmacy for one year.

(4) Any changes made in the pharmacy's operation based upon the review and investigation shall be recorded.

### ***MEDICATION ERROR REVIEW FORM EXAMPLE***

Patient's Name: \_\_\_\_\_ Phone # \_\_\_\_\_

Date of the Medication Error: \_\_\_\_\_

Pharmacy Staff involved in Error: \_\_\_\_\_

Area in Pharmacy where error occurred: \_\_\_\_\_

Pertinent data and other information relating to Med. Error: \_\_\_\_\_  
\_\_\_\_\_

Documentation of any patient or prescriber contact: \_\_\_\_\_  
\_\_\_\_\_

Findings and determinations generated by the Q.A. Review: \_\_\_\_\_  
\_\_\_\_\_

Recommended changes to pharmacy policy, procedure, systems, or processes: \_\_\_\_\_  
\_\_\_\_\_

Additional Information: \_\_\_\_\_  
\_\_\_\_\_

Date this report was prepared: \_\_\_\_\_

Person Preparing Report: \_\_\_\_\_

# REFERENCES TO CHAPTER 5

1. Title 16, Calif. Code of Regs, Sec. 1764
2. *Ibid.* at Sec. 1764
3. Calif. Civil Codes, Sec. 56.10[b]
4. *Ibid.* at Sec. 56.10[c]
5. 45 CFR 164.520
6. 45 CFR 164.501
7. Office of Civil Rights HIPAA Privacy, *Uses And Disclosures For Treatment, Payment, And Health Care Operations*, Dec. 3, 2002 Report.
8. 45 CFR Part 160 and Subparts A and E of Part 164
9. 45 CFR 160.103
10. 45 CFR 164.520
11. Office of Civil Rights HIPAA Privacy, *General Overview Of Standards For Privacy Of Individually Identifiable Health Information*, Dec. 3, 2002 Report.
12. 45 CFR 164.502[a][1][iii] and 164.530[c]. Also Office of Civil Rights HIPAA Privacy, *Incidental Uses And Disclosures*, Dec. 3, 2002 Report.
13. 45 CFR 164.502[b] and 164.514[d]
14. 45 CFR 164.510[b][3]
15. Calif. Family Law Codes, Secs. 6920-6921 & 7050-7052
16. *Ibid.* at 6922
17. 45 CFR 164.502[e], 164.504[e], and 164.532[d][e]
18. Office of Civil Rights HIPAA Privacy, *Business Associates*, Dec. 3, 2002 Report
19. 45 CFR 164.510[b]
20. Office of Civil Rights HIPAA Privacy, *Uses And Disclosures For Treatment, Payment, and Health Care Operations*, Dec. 3, 2002 Report.
21. Calif. Bus. & Prof. Code, Sec. 4125[a]
22. *Ibid.* at 4125[b]
23. Title 16, Calif. Code of Regs, Sec. 1711[a]
24. *Ibid.* at Sec. 1711[b]
25. *Ibid.* at Sec. 1711[c]
26. *Ibid.* at Sec. 1711[c]
27. *Ibid.* at Sec. 1711[d]
28. *Ibid.* at Sec. 1711[d]

29. *Ibid.* at Sec. 1711[e]
30. *Ibid.* at Sec. 1711[e]
31. *Ibid.* at Sec. 1711[f]
32. *Ibid.* at Sec. 1711[h]





## CHAPTER 6

# **LAWS ENCOURAGING THE PHARMACIST TO PARTICIPATE IN PATIENT CARE SERVICES**

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Since the late 1980s there has been a trend in pharmacy practice in California, as well as in other states, to involve the pharmacist more directly in the care and welfare of patients receiving prescription medications. California laws are now encouraging the pharmacist, and in some cases mandating that the pharmacist becomes involved in-patient care. Examples of such laws that encourage the pharmacist's participation in the patient's health and well-being are:

- Setting up blood pressure monitoring programs.<sup>1</sup>
- Allowing pharmacists to do certain physical assessments, order drug related laboratory tests, provide drugs by injection, and initiate or adjust patient therapy under physician-guided protocols. Pharmacists have more recently been given the same opportunities as PAs, NPs, CNMs, and NDs in writing prescriptions for drugs pursuant to a prescriber directed protocol, along with being able to register with the DEA for the furnishing of Scheduled controlled substances if authorized to do so according to a prescriber's protocol.<sup>2</sup>
- Counseling patients on the proper use of their drugs and what to both expect and be concerned about regarding the use of a prescription medication.<sup>3</sup>
- Maintaining of patient medication profiles to ensure through drug utilization review (DUR) that patients are properly taking their medications, that drug misuse or abuse is addressed, that allergy issues are carefully screened, and that the inappropriate use of synergistic combinations of drugs is avoided.<sup>4</sup>
- Performing skin punctures for both training patients how to do their own skin puncture testing, as well as assessing various clinical conditions such as blood sugar and blood cholesterol levels.<sup>5</sup>
- Participation in immunization programs.<sup>6</sup>
- Furnishing emergency oral contraceptives.<sup>7</sup>

## **PHARMACIST CONSULTATION WITH THE PATIENT**

For every new prescription that a patient receives, the pharmacist is required by law to orally consult with the patient regarding the following:<sup>8</sup>

- How to use the medication.
- The importance of complying with directions on the label.
- How to store the medication.
- Advising the patient of the common severe adverse drug reactions and/or drug interactions.

If in the judgment of the pharmacist, the patient may also need to be advised on the following matters:<sup>9</sup>

- Name and description of the new drug.
- Route of administration and dosage form
- Dosage and duration of therapy.
- Any special directions for use and storage.
- How to prepare the drug for administration if required.
- Techniques for self-monitoring the drug therapy.
- Methods for avoiding common severe side effects or known drug interactions.
- Actions to be taken if a side effect or drug interaction should occur.
- What to do if a dose of the drug is missed.

Additional information regarding pharmacist-patient consultation is discussed in Chapter 8: *Patient Oral And Written Communications* under the section heading entitled, *“What Information Is The Pharmacist Required To Give To The Patient During A Drug Consultation Session?”*

### ***THE MAINTENANCE AND USE OF PATIENT MEDICATION PROFILES WITHIN THE PHARMACY***

Each community pharmacy is responsible by law for maintaining patient medication profiles on patients who routinely have their prescription medications filled or refilled at a California pharmacy.<sup>10</sup> A patient's medication profile must serve to fulfill a "Drug Utilization Review (DUR)" purpose requiring of the pharmacist to review a patient's medication profile each and every time a prescription is filled or refilled.<sup>11</sup> A careful review of a patient's medications is mandated by law to ensure that problems that may be associated with medication allergies, idiosyncratic drug reactions, drug misuse or abuse, and synergistic relationship between drugs being used is prevented and the patient educated on the consequences of taking drugs under these described circumstances.

A patient's medication profile record must be kept by a pharmacy for **at least one year after the last entry.**<sup>12</sup>

Information usually maintained on a patient's medication profile in a pharmacy is further described in Chapter 7: *Dealing With Written Documentation In Pharmacy Practice* under the section entitled, "*Other Documentation And Records That Must Be Kept By The Pharmacy – 1. The Patient Drug Profile.*"

### ***MAY A PHARMACIST IN ADDITION TO ADJUSTING A PATIENT'S DRUG THERAPY, UNDER THE SCOPE OF PRACTICE GUIDELINES, ALSO INITIATE THE THERAPY PURSUANT TO A PRESCRIBER'S PROTOCOL?***

Over the years, pharmacists in various practice settings have had the opportunity to expand their services to include direct patient care responsibilities. Originally this so-called expanded role began in various institutional settings such as acute care facilities, extended or skilled care facilities, and in clinics. Recently, community pharmacy practitioners may also engage in these expanded patient care

roles.<sup>13</sup> The major requisite in order for the pharmacist to function in these expanded roles has been the result of forming alliances with prescribers who support the pharmacist's role expansion by developing comprehensive protocols stating what a pharmacist may do under the protocol. While much of this role extension under protocol has been touched upon in *Chapter 3: Pharmacy's Cast of Characters* under the section entitled, "*What Duties Are Generally Expected Of A Registered Pharmacist,*" it is important to reiterate those extended scope of practice items for those pharmacist's in the community setting that may be working with a physician or group of physicians under a protocol that allows the pharmacist to engage in the following patient care activities:<sup>14</sup>

- Ordering or performing routine drug therapy related patient assessment procedures, including temperature, pulse, and respiration.
- Ordering drug therapy related laboratory tests.
- Administering drugs and biologicals by injection pursuant to a prescriber's order.
- Initiating and adjusting the drug regimen of a patient according to written protocol standards.

In order for this extended scope of practice to be undertaken by a pharmacist in a patient care setting, including a community pharmacy setting, the following must occur:<sup>15</sup>

- There must be at least one physician who supports these extended services on behalf of a pharmacist to be provided to that physician's patients.
- The physician(s) must work with a pharmacist or pharmacists, and possibly a registered nurse or nurses who will be involved in the direct care of the patient.
- There must be a written protocol or policy that describes the pharmacist's duties associated with his or her extended roles.
- The medical records for a patient being followed under the protocol must be available to both the patient's physician and the pharmacist. Particularly important is



if the pharmacist is authorized to initiate drug therapy pursuant to a prescriber protocol, then the pharmacist must have access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advise.<sup>16</sup>

- That the procedures to be performed by the pharmacist pursuant to the protocol relate to a condition for which the patient has first been seen by a physician.
- Any change, initiation, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

### ***THE PHARMACIST PERFORMING SKIN PUNCTURES FOR TRAINING AND ASSESSING PATIENTS***

The law has been expanded in this area. Previously, a pharmacist could only show a patient how to draw a small sample of his own blood in order for the patient to do his own testing on a routine basis such as in the case of monitoring blood-glucose levels for a diabetic patient.

Today, a pharmacist may perform a skin puncture “in the course of performing routine patient assessment procedures.” The law defines the skin puncture parameters for the pharmacist and what a routine patient assessment means:<sup>17</sup>

- A procedure that a patient could, with or without a prescription, perform for him- or herself, and
- Clinical laboratory tests that are classified as waived or moderate under the federal Clinical Laboratory Improvement Amendments of 1988.

This addendum to the law now allows the pharmacist to draw blood from a patient for the testing of blood-glucose levels and cholesterol levels. If the patient requests the results of these blood tests for either themselves or his or her

physician, the pharmacist, based on the wording of the statute, must honor that request.

### ***THE PHARMACISTS INVOLVEMENT IN IMMUNIZATION PROGRAMS***

According to the California Business and Professions Code, Section 4052(a)(9), “A pharmacist may administer immunizations pursuant to a protocol from a prescriber.” The pharmacist who wishes to engage in an immunization program must do so under a comprehensive protocol developed by the prescriber or a group of prescribers. Subject matter that would be included in the written protocol would cover at least the following:

- A statement that a physician would be responsible for overseeing the immunization program. This would not necessarily require that the prescriber be physically present at the program.
- A clear description of the type of immunization that will be provided and the class of patients who would receive it, and those who would not receive it (possibly due to pre-existing medical conditions). If there were a shortage on the supplies of the immunization product, guidelines on the priority of administration based on age, medical condition, and environmental exposure would be created.
- An indication that the prescriber would not be required to provide a prescription order for each immunization recipient.
- A statement as to the action to be taken if a recipient is injured as the result of the immunization.

A pharmacist who engages in providing patient immunizations should consider the ways in which he or she may protect him- or herself from liability:

- Know and follow the applicable laws, developed protocol standards, and the vaccine manufacturer’s guidelines for administration.

- Engage in a training program that will develop the necessary skills and experience required to provide immunizations. Presently, various pharmacy-related organizations provide certification programs for pharmacists who wish to participate in immunization projects.
- Maintain a personal pharmacist insurance policy that provides coverage in the case of an immunization misadventure. Since pharmacists may now participate in immunization programs under the authority of the law, one's insurance policy should cover any negligent acts in this area. However, it is still a good idea to contact the insurance carrier to be assured of the coverage before partaking in an immunization program.
- The pharmacist should know the policy and liability coverage of the immunization product by the manufacturer. They will generally have coverage for any adverse effects or allergic reactions that occur.

Both the federal and state governments have put into place a series of laws that will provide protection against vaccine product liability for those licensed personnel who administer immunizations if such administrations are associated with:

- State health department organized immunization programs.
- Charitable organizations where those providing immunizations to such organizations are service volunteers.
- Administering immunizations in accordance with state or federal laws.
- Programs that are funded under one of four federal community health service programs and as such are indemnified by the Federal Tort Claims Act.

Generally, the immunity protection provided to those who administer the immunizations is for any adverse effect caused by the drug product and not usually for any act of negligence on the part of the individual who administers the injections.

The National Vaccine Injury Compensation Program (NVICP – basically established to award compensation to children who may be injured by an immunization product) maintains an insurance fund for those persons injured by an immunization product. Compensation allocated from this fund has limitations (e.g. for death-related claims, the total benefit allowed by law is presently \$250,000). The NVICP has established criteria allowing it to recognize an adverse or allergic reaction associated with the immunization or vaccine product. For example, with the administration of a *Measles Vaccine* the following adverse effects could be noted within a specific time period after the immunization was given:

- *Anaphylaxis/Anaphylactic shock* — within 4 hours
- *Encephalopathy/Encephalitis* — within 5-15 days
- *Residual seizure disorder* — within 5-15 days
- *Chronic arthritis* — within 42 days

If any of the above were to occur, the patient could have entitlement to some compensation under the NVICP arrangement.

### ***BLOOD PRESSURE MEASUREMENTS CONDUCTED BY THE PHARMACIST***

Perhaps one of the earlier patient care services provided by pharmacists was their ability to monitor patient blood pressure. Various organizations such as the American Red Cross and the American Heart Association, as well as other certifying entities such as Schools of Pharmacy have been the major training groups for pharmacists in performing blood pressure measurements.

The law basically states what a pharmacist is authorized to do when taking a patient's blood pressure. Under the authority of the law a pharmacist may:<sup>18</sup>

- Inform the patient of the result;
- Render an opinion as to whether the reading is within a high, low, or normal range; and
- Advise the patient to consult a physician if necessary.

***PHARMACIST ADMINISTERING IN A SKILLED  
NURSING FACILITY INFLUENZA AND  
PNEUMOCOCCAL IMMUNIZATIONS PURSUANT  
TO A STANDING ORDER***

Both a registered nurse and pharmacist may administer in a skilled nursing facility (SNF) both influenza and pneumococcal immunizations pursuant to standing orders and without patient-specific orders if the following is met:<sup>19</sup>

- The SNF medical director has approved the immunization standing orders established by the facility.<sup>20</sup>
- The standing orders meet the recommendations of the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention.

***PHARMACIST DISCRETION IN PROVIDING  
EMERGENCY SUPPLIES OF DRUGS WITHOUT  
REFILL AUTHORIZATION***

Perhaps one of the most common areas where the pharmacist must exercise his or her own judgment on a day-to-day basis to promote good patient care is in the area of providing a patient with a prescription drug where there are no refills indicated and the prescriber cannot be immediately reached to approve a continuation of the prescription drug. The law allows the pharmacist discretion in this area for the emergency refilling of both nonscheduled and Schedule III, IV and V controlled substances.

For the emergency filling of either a nonscheduled drug or a Schedule III, IV or V controlled substance the law specifically states that in the “pharmacist’s professional judgment, failure to refill the prescription might interrupt the patient’s ongoing care and have a significant adverse effect on the patient’s well-being.”<sup>21</sup>



If the emergency refill is for a nonscheduled drug, the pharmacist has discretion, based upon the circumstances, in providing the patient with a full refill of his or her medication or a reasonable quantity of the drug.<sup>22</sup>

If the emergency refill is for a Schedule III, IV, or V drug, the pharmacist has discretion in providing the patient with only a reasonable quantity of the drug until the prescriber can be contacted.<sup>23</sup> Schedule II controlled substances cannot be refilled under similar circumstances without the execution of a new written security prescription or an emergency call to the pharmacy by the prescriber to continue the Schedule II drug followed by the issuing of a new security prescription within 7 days after telephoning in the emergency order. The emergency refill provision for a Schedule III, IV, or V controlled substance must be based upon the pharmacist's judgment that if the patient did not receive the drug there might be an immediate hazard to the patient's health and welfare or the patient might experience severe suffering.<sup>24</sup>

When the pharmacist plans to provide a reasonable quantity or full refill (in the case of non-scheduled prescription drugs) of the prescription drug to the patient who does not have any further refills on their prescription, besides providing the drug according to the above noted discretionary criteria, the pharmacist must also consider the following:

- To provide to a patient only a quantity of the drug that equates to a reasonable period of time in which the prescriber can be contacted for his or her refill approval.<sup>25</sup>
- To place the reasonable supply of the drug in a new container that is properly labeled.<sup>26</sup>
- That there is evidence that the patient has been taking the prescription medication regularly and according to the prescriber's instructions, and that if a reasonable supply is not given, the patient may miss a necessary dose.
- That the pharmacist shall inform the patient that there are no refills on the prescription and that the patient's

prescriber was not available to authorize further refills, but that in the pharmacist's judgment the patient is to continue the medication.<sup>27</sup>

- That prior to providing the patient with a reasonable quantity of the medication, the pharmacist shall make every reasonable effort in contacting the prescriber.<sup>28</sup>
- That the pharmacist shall record on the back of the prescription the date and reasonable amount of drug given, the reason for continuing the drug, and the initials of the pharmacist filling the prescription.

Regarding prescription documentation details in the refilling of both nonscheduled drug and scheduled controlled substance prescriptions where no refills are available, also refer to *Chapter 7: Dealing With Written Documentation In Pharmacy Practice* under the section entitled, "What Information Must Be Recorded Every Time A Prescription Is Refilled;"

A pharmacist may also provide reasonable quantities of drugs to patients who have received prescriptions for such drugs where there are neither refills nor the patient has his or her prescription record at the pharmacy where the request is made, if such a request is made during a government declared "State of Emergency." While the rules for providing reasonable quantities of drugs to patients who may come to you for the first time with prescription containers from other pharmacies during the declared state of emergency, the pharmacist must base his or her judgment of providing a reasonable supply of the drug to the patient on the same principles noted above to prevent patient harm or suffering. Regarding a discussion on the pharmacist's role during a declared state of emergency in the refilling of prescriptions from other pharmacies, please refer to the following chapters:

- *Chapter 7: Dealing With Written Documentation In Pharmacy Practice*, the section entitled, "Other Documentation And Records Which Must Be Kept By The Pharmacy – (6. Records Concerning The Furnishing Of Drugs During A State Of Emergency)," and

- *Chapter 14: Rules Concerning Schedule III, IV And V Controlled Substances* under the section entitled, “*If There Are No Refills On A Schedule III, IV or V Prescription, May An Emergency Supply Be Given To The Patient If the Prescriber Is Unavailable?*”

### ***THE PHARMACIST’S ROLE IN THE PROVISION OF EMERGENCY ORAL CONTRACEPTIVE DRUG THERAPY***

There are now several ways in which emergency oral contraceptives can be obtained. One way is by a physician’s prescription. A second way is by means of having a specially trained pharmacist provide the emergency contraception pursuant to the California State Protocol or by a physician directed protocol. And the last and most recent was the approval of Plan B on August 24, 2006 that allows for the sale by pharmacies of a specific emergency oral contraceptive (levonorgestrel) over-the-counter.

#### ***Physician’s Prescription Order For An Oral EC***

If a physician writes a prescription for an emergency oral contraceptive the pharmacist must follow all the necessary labeling and consultation requirements as he or she would for any prescription. The pharmacist upon dispensing the prescription on a first time provision must by law instruct the patient on how to use the drug, the importance of compliance, how to store the drug, and the common severe adverse effects or drug interactions associated with the emergency oral contraceptive.<sup>29</sup> The physician may prescribe a variety of progestational alone or in combination with an estrogenic substance usually in one or two doses taken within a specific period of time after sexual intercourse; and may prescribe the emergency oral contraceptive for a patient who is under the age of 18. In the case where the emergency oral contraceptive is written by a physician, the pharmacist is not allowed to charge the administrative fee of up to \$10, nor be required to have special training for dispensing this category of drug. This latter point of charging an administrative fee and having special training is associated with providing emergency oral

contraception under a state or physician directed protocol as discussed below.

*Dispensing Oral ECs Pursuant To A State  
Or Physician-Directed Protocol*

A pharmacist who has completed a training program on emergency contraception which includes, but is not limited to, the pharmacological actions of oral contraceptives, conduct regarding sensitive communications, quality assurance, referral to additional services, and documentation is eligible for participating in the provision of emergency contraceptive drug therapy.<sup>30</sup> A standardized protocol must be developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice in order for the pharmacist to furnish the emergency contraceptive drugs to patients.<sup>31</sup> The protocol developed or followed must be in accordance with the following arrangements:<sup>32</sup>

- The protocol may either be developed by a pharmacist and an authorized prescriber who is acting within his or her scope of practice.<sup>33</sup> In the alternative, the pharmacist may also follow a protocol that has statewide approval by the California Board of Pharmacy, the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association and other appropriate organizations. Both Boards will be responsible for ensuring that pharmacists follow the government created protocol when emergency contraception is furnished to the patient.<sup>34</sup>
- The pharmacist must complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.<sup>35</sup>
- The pharmacist must provide the following service or information when a patient either requests or is furnished with an emergency oral contraceptive (EC).<sup>36</sup>
  - Ask the patient if they are allergic to any medications.



- Insure that the timing in the use of the emergency contraceptive is appropriate. The EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse (the EC effectiveness declines gradually over five days and the EC use will not interfere with an established pregnancy).
- Provide to the patient receiving the EC with a fact sheet and review any questions the patient may have regarding the use of the EC. The fact sheet should include, but is not limited to the following:<sup>37</sup>
  - Indications for use of the drug.
  - Appropriate method for using drug.
  - Need for medical follow-up.
  - Other pertinent and related information.
- If the EC services are not available at the pharmacy or the pharmacist declines to furnish the EC because of specific beliefs, or did not choose to be involved in this program, that pharmacist will refer the patient to another EC provider in the area.
- The pharmacist may dispense the EC medication in advance of the patient's anticipated need for emergency contraception.
- The pharmacist shall dispense EC therapy from an established list of oral contraceptive agents routinely employed in the EC program. The list will indicate the number of tablets of the EC to be taken per dose. The usual dosage will be anywhere from 1 to 5 tablets of a specific oral contraceptive drug to be taken in one dose within 120 hours of the unprotected intercourse. In some cases doses may be divided into two doses with the second dose taken 12 hours after the first dose.
- The pharmacist will also provide the patient with information regarding adjunctive medications indicated for nausea and vomiting associated with taking EC medications.



- The pharmacist will document each EC supply dispensed to a patient and will document the provision of the EC in the patient's medication profile.<sup>38</sup>
- The patient who receives and EC agent shall have this information held as confidential by the pharmacy.
- The pharmacist may not require a patient to provide individually identifiable medical information that is not specified in the patient medication profile regulation of Title 16, Calif. Code of Regulations, Section 1707.1.<sup>39</sup>

A unique condition of the program once the protocol has been established either by a physician working with a pharmacist or employing the statewide standardized protocol, is that no prior examination by a physician is required and that the pharmacist is the one who makes the decision as to whether or not a patient should receive the emergency contraception drug therapy based upon the standards established in the protocol.

Concerning the reimbursement by the patient or third party payers for the provision of oral contraceptive, the pharmacy may not charge a patient a separate consultation fee, but may charge an **administrative fee not to exceed ten dollars (\$10)** above the retail cost of the drug. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of the EC drug shall not be required to pay an administrative fee.<sup>40</sup> These patients shall, however, be required to pay co-payments pursuant to the terms and conditions of their coverage.

An additional point is that under the protocol, the trained pharmacist may provide the emergency oral contraceptive to patients under the age of 18.

*Over-The-Counter Sale Of An  
Emergency Oral Contraceptive*

Plan B allows the use of two tablets of levonorgestrel 0.75mg only to be sold over-the-counter at a pharmacy. The

F.D.A. has established definitive rules regarding the sale of this drug over-the-counter by pharmacies:<sup>41</sup>

- The Plan B Oral Emergency Contraceptive (levonorgestrel) may only be sold at pharmacies, and not at other retail businesses.
- The oral EC must be kept behind the pharmacy counter and not placed on the external shelves for patients to have easy access to it.
- The oral EC may only be sold to persons 17 years of age or older. The purchaser can be required to show identification upon request. Males, as well as family members or friends can purchase the product as long as they are 17 years or older.
- The purchaser may purchase more than one package whether it is for immediate or future need.
- No administrative fee may be charged.
- No consultation appears to be required by the pharmacist or pharmacist intern upon making the sale. It appears, conservatively speaking, that only the pharmacist and the pharmacist intern, under the supervision of the pharmacist, are the only ones that can transact the sale for the oral EC.
- The Plan B oral EC can also be written for by a physician as a prescription, and must be treated as such. If written by a physician, the physician may prescribe it for a patient under the age of 17.

### ***HYPODERMIC SYRINGE/NEEDLE EXCHANGE PROGRAM***

There is recent legislation that will most probably include pharmacists in becoming involved in public programs that allow for hypodermic syringe/needle exchange programs. Such programs exempt “public entities” and their employees from criminal prosecution for distributing hypodermic needles and syringes to participants involved in a clean needle and syringe exchange program. Such programs will only be initiated pursuant to a declaration of an emergency by the public entity.<sup>42</sup>

**REFERENCES TO CHAPTER 6**

1. Calif. Bus. & Prof. Codes, Sec. 4103
2. Calif. Bus. & Prof. Code, Secs. 4040, 4052, & 4060, & Calif. Health & Safety Code, Sec. 11150
3. Title 16, Calif. Code of Regs., Sec. 1707.2
4. *Ibid.* at Secs. 1707.1 & 1707.3
5. Calif. Bus. & Prof. Codes, Sec. 4052.4
6. *Ibid.* at Sec. 4052[a][9]
7. *Ibid.* at Sec. 4052.3
8. Title 16, Calif. Code of Regs., Sec. 1707.2[c]
9. *Ibid.* at Sec. 1707.2[d]
10. *Ibid.* at Sec. 1707.1
11. *Ibid.* at Sec. 1707.3
12. *Ibid.* at Sec. 1707.1[a][2]
13. Calif. Bus. & Prof. Code, Sec. 4052
14. *Ibid.* at Sec. 4052[a]
15. *Ibid.* at Secs. 4052[a][5], 4052.1, & 4052.2
16. *Ibid.* at Sec. 4052.2
17. *Ibid.* at Sec. 4052.4
18. *Ibid.* at Sec. 4103
19. Calif. Health & Safety Codes, Sec. 1261.3
20. Title 22, Calif. Code of Regs., Sec. 72305
21. *Ibid.* at Sec. 4064[a]
22. *Ibid.* at Sec. 4064[a]
23. Calif. Health & Safety Codes, Sec. 11201
24. *Ibid.* at Sec. 11201
25. *Ibid.* at Sec. 11201 and Calif. Bus. & Prof. Codes, Sec. 4064
26. Title 16, Calif. Code of Regs., Sec. 1717[a]
27. Calif. Bus. & Prof. Codes, Sec. 4064[b] and Calif. Health & Safety Codes, Sec. 11201
28. Calif. Bus. & Prof. Codes, Sec. 4064[d] and Calif. Health & Safety Codes, Sec. 11201
29. Title 16, Calif. Code of Regs., Sec. 1707.2[c]
30. Calif. Bus. & Prof. Codes, Sec. 4052.3[b]
31. *Ibid.* at Sec. 4052.3[a][1]
32. *Ibid.* at Sec. 4052.3[a][2]

33. *Ibid.* at Sec. 4052.3[a][2]
34. *Ibid.* at Sec. 4052.3[a][2]
35. *Ibid.* at Sec. 4052.3[b]
36. Title 16, Calif. Code of Regs., Sec. 1746
37. *Ibid.* at Sec. 1746
38. Title 16, Calif. Code Code, of Regs., Secs. 1707.1, 1707.3, & 1746
39. *Ibid.* at Secs. 1707.1 & 1746 & Calif. Bus. & Prof. Codes, Sec. 4052.3
40. *Ibid.* at Sec. 4052.3[c]
41. U.S. FDA Report: "FDA's Decision regarding Plan B: Questions & Answers (Aug. 24, 2006)
42. Calif. Health & Safety Code, Sec. 11364.7





## CHAPTER 7

# DEALING WITH WRITTEN DOCUMENTATION IN PHARMACY PRACTICE

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***WHAT INFORMATION IS REQUIRED ON  
A PRESCRIPTION SUBMITTED FOR FILLING  
BY A PHARMACY?***

When a prescription is issued by a prescriber in writing (on regular prescription blanks for non-scheduled drugs or by use of California issued security prescription forms for scheduled drugs) the following information must be provided on that prescription before it can be filled:<sup>1</sup>

- If written by the prescriber, the signature of the prescriber, or furnisher in the case of physician assistants, nurse practitioners, certified nurse midwives, naturopathic doctors or pharmacists acting pursuant to a prescriber directed protocol.
- The name and address of the patient.
- The name and quantity of the drug or device prescribed.
- The directions for use.
- The date of issuance by the prescriber. For written controlled substance prescriptions the date must be in the handwriting of the prescriber.
- The name, address, and telephone number of the prescriber, either rubber-stamped, typed, or printed by hand or typeset.
- The prescriber's or furnisher's license classification, and his or her federal registry number. If a controlled substance is prescribed or furnished by a non-licensed prescriber as noted above it must be furnished pursuant to a prescriber's authorized protocol.
- Indication of the condition for which the drug is being prescribed, if requested by the patient and noted on the prescription.

***WHAT IS REQUIRED FOR PRESCRIPTIONS THAT  
ARE TRANSMITTED ORALLY OR ELECTRONICALLY  
TO THE PHARMACY?***

***Oral Transmission of Prescriptions***

A prescription that is orally (commonly communicated over the telephone) transmitted from a licensed prescriber for both non-scheduled controlled substances and Scheduled III, IV, and V controlled substances, must be reduced to writing on the pharmacy's regular prescription forms as soon as received orally. These prescriptions are then stored in hard copy files. Schedule II prescriptions may not be accepted orally unless under an emergency circumstances (see Chapter 13, the material presented under the subtitle, "*May A Prescriber Order A Schedule II Controlled Substance For A Patient Over The Phone If It is For An Emergency Circumstance?*" for a discussion on accepting an oral Schedule II prescription under an exception).<sup>2</sup>

***Fax Transmission of Prescriptions***

Non-Scheduled control substance prescriptions that are transmitted by fax (from the fax of the prescriber's office to the fax at the pharmacy) are acceptable for filling if signed by the prescriber, along with the name or identifiable initials of the party forwarding the prescription to the pharmacy.<sup>3</sup> While not clear under present existing law, faxed prescriptions for Schedule III, IV, or V controlled prescriptions transmitted from the prescriber's office to the pharmacy may be acceptable if they are placed and signed by the prescriber on the State of California's special security forms allowed for fax transmission. If a faxed prescription for a Schedule III, IV, or V controlled substance is sent by the prescriber on a non-security form prescription, the pharmacy can probably call the doctor to confirm the faxing of the controlled substance prescription, and treat it like an oral, phoned-in prescription and transfer the information

onto the pharmacy's prescription blanks before filling, and then file as a hard copy. Schedule II control substance prescriptions may not be sent by fax from the prescriber's office.

*Electronic Transmission (e.g. Computer To Computer)  
of Prescriptions*

An electronic prescription transmitted for a non-scheduled controlled substance by a licensed prescriber shall not be required to have that prescription reduced to writing or to hard copy if it is stored electronically for up to three years from the last entry on it, and the pharmacy is able upon a request from the Board, to immediately produce the prescription with all up-to-date information associated with it.<sup>4</sup>

The allowance of Schedule controlled substance drug prescription orders to be sent by data transmission (e.g. computer to computer) is to follow the D.E.A.'s federal guidelines under "*E-Prescribing*." The rules for "*E-Prescribing*" are addressed in Chapter 14 under the section entitled, "*E-PRESCRIBING OF CONTROLLED SUBSTANCES*."

A prescription that is electronically transmitted from a prescriber may have the prescriber's address, license classification, and federal registry number, or the address of the patient may be omitted from the electronic prescription if they are on file and readily retrievable in the receiving pharmacy.<sup>5</sup>

In writing a prescription, the prescriber is at liberty to use commonly understood abbreviations. Such abbreviations will not invalidate an otherwise valid prescription.<sup>6</sup> Under no circumstances should a pharmacist compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity, or alteration, without first contacting the prescriber to clarify any unclear aspect of the written prescription.<sup>7</sup> Even after clarifying an unclear matter regarding a prescription, if the pharmacist knows or has reason to know that a prescription was not issued for a



legitimate medical purpose he or she should not dispense the medication, especially in the case of a controlled substance prescription.<sup>8</sup>

### ***WHAT INFORMATION MUST BE PLACED ON A FILLED PRESCRIPTION BEFORE IT IS FILED AWAY?***

After a prescription is filled and before it is filed away, the following information should be recorded on the prescription:<sup>9</sup>

- A method by which the prescription may be retrieved once filed away. The most common method of filing is by the use of a “**prescription number**”; however, other methods of retrieval may be used, such as filing by the patient’s name.
- The **date when the prescription was filled**. This may be different than the date it was written or requested by the prescriber.
- The **initials of the dispensing pharmacist**. Any prescription filled by the pharmacy intern or technician must have the label initialed by the pharmacist.
- The **brand name of the drug or device**; or, if a generic drug or device is dispensed, the distributor’s or manufacturer’s name. When a generic drug is used, if it has a distinct trade name, that name may be used on the prescription; otherwise, the **manufacturer’s name** must be used.
- The **price** charged to the patient. This is not required by statute or regulation but is considered ethically appropriate.

Every time a prescription is refilled, a written record of each refill must be kept stating the date refilled, the quantity dispensed (if different from what was originally requested by the prescriber), and the initials or name of the dispensing pharmacist.<sup>10</sup> Any time there is a change in the originally written prescription, such as a change in the drug,

strength, prescriber, or directions for use, a new prescription must be written, unless a complete record of all such changes is otherwise maintained.<sup>11</sup>

A prescription that is orally transmitted must be reduced to writing as soon as possible or stored electronically. The written or electronically stored record must identify both the person who transmitted it and the pharmacist who received it (identifying initials may be used). If the prescription happens to be dispensed by another pharmacist, his or her initials will also be required on the filed prescription that is to be placed in the record files.<sup>12</sup>

### ***WHAT INFORMATION IS REQUIRED ON A PRESCRIPTION LABEL?***

The information required by law to be placed on a label affixed to a prescription container to be dispensed to a patient must include the following:<sup>13</sup>

- The name and address of the pharmacy.
- A prescription number or some other means of identifying the prescription.
- The name of the patient.
- The name of the prescriber and license category, or furnisher if the furnisher should be a PA, NP, CNM, ND or pharmacist acting in accordance with a licensed prescriber's written protocol authorizing the furnishing of specific prescription drugs.
- The date of issue.
- The name of the drug. Either the manufacturer's trade name, or the generic name along with the name of the manufacturer can be used (a commonly used abbreviation identifying the drug is also acceptable). Preparations containing two or more active ingredients (usually when compounded) may be identified by the manufacturer's trade name, or the commonly used names of the active ingredients.
- The strength of the drug.
- The quantity of the drug dispensed.

- The directions for use.
- The expiration date. (See discussion below on what qualifies as an appropriate expiration date.)
- The reason or reasons for which the medication was prescribed if noted on the prescription by the prescriber and requested by the patient.
- Commencing on January 1, 2006 the prescription label (or auxiliary label affixed to the prescription container) shall also contain a description of the drug dispensed. That description shall include:<sup>14</sup>
  - The color of the tablet or capsule.
  - The shape of the tablet or capsule.
  - Any identification code that appears on the tablets or capsules.

*[The color, shape, or identification code will not have to be placed upon the label if:*

- *The prescription is dispensed by a veterinarian.*
- *For the first 120 days the drug is on the market and for the 90 days during which the national reference fill has no description on file.*
- *The dispensed medications where no physical description exists in any commercially available database.*
- *The drug is for inpatient use. The description on the label ruling only applies to outpatient pharmacies.]*

Many practicing pharmacists believe that the law requires the initials of the filling pharmacist to appear on the label, along with the number of remaining refills. It is perfectly appropriate to place this information on the label; however, it appears that neither the statutes nor the regulations require that this information be on the label if the entire prescription is processed by a pharmacist. The reason that this information is not mandated by law can probably be attributed to the fact that these two items already appear on the filed prescription.

There is, however, a requirement that if the pharmacy technician or pharmacist intern prepares the drug to be dispensed, then the supervising pharmacist's initials must appear on the label.<sup>15</sup> This indicates that the pharmacist provided the final check of the medication before it is to be dispensed to the patient.

Keep in mind that the law does not yet require the placing of lot numbers on either the prescription label or the prescription itself. There is, however, a requirement for lot numbers to be recorded when the pharmacist prepares compounded products for future furnishings and extemporaneous unit dose drugs prepared in the pharmacy.<sup>16</sup>

### ***THE PATIENT-CENTERED PRESCRIPTION LABEL REQUIREMENTS***

The California Board of Pharmacy will require a standardized prescription label on all prescription medications dispensed. The new prescription label requirements were to be put into effect either before or by January 1, 2011. In developing new prescription label standards, the Board has taken into account the following:<sup>17</sup>

- Medical literacy to allow increased understandability.
- Improved and possibly more complete directions for use.
- Improved font types and sizes to ensure that those with limited vision capability will be able to read the contents of the label.
- The provision of patient-centered information to enhance better compliance with the taking of the prescription medications.
- The needs of patients with limited English proficiency.
- The needs of senior citizens.
- The technology requirements needed to implement the standard.

Thus, the purpose of the new labeling requirement is to emphasize on the label information of greatest importance (to be highlighted in color using bolder or larger type and enclosing in a white box area) which shall include: patient name, name of the drug and strength, directions for use, and purpose (if entered onto the prescription by the prescriber). Fifty percent (50%) of the label must be dedicated to these elements, and they must be printed in at least 10 point *sans serif* font, and if requested by the patient, in 12-point *sans serif* font to accommodate for vision deficiencies.<sup>18</sup>

ABC Pharmacy (323) 123-4567	Date Filled: June 1, 20XX
123 No. Main St	
Los Angeles, CA 90000	
Rx #: 7891011	
Mary Jones	
Lipotor 10 mg Tablets	
Take 1 tablet in the morning every day.	
Treat high Cholesterol.	
Dr. B. Smith, M.D.	Quantity: 60 Expires: June 1, 20xx
Oblong white tablet, Code: PD 155	Refills: 2

Label Size: 8.29 x 5.43 cm, Font: Sans Serif, 10 &/or 12 pt.  
(The label above is one of many examples that may be used)

In addition, when applicable, example directions for use shall employ one of the following phrases consistent with the intent of the prescriber so that the administration directions shall be clear to the patient:<sup>19</sup>

- 1) Take 1 (insert appropriate dosage form) at bedtime.
- 2) Take 1 (insert appropriate dosage form) in the morning.
- 3) Take 1 (insert appropriate dosage form) in the morning, and take 1 (insert appropriate dosage form) at bedtime.



- 4) Take 1 (insert appropriate dosage form) in the morning, 1 (insert appropriate dosage form) at noon, and 1 (insert appropriate dosage form) in the evening.
- 5) Take 1 (insert appropriate dosage form) in the morning, 1 (insert appropriate dosage form) at noon, and 1 (insert appropriate dosage form) in the evening, and 1 (insert appropriate dosage form) at bedtime.
- 6) If you have pain, take \_\_ (insert appropriate dosage form) at a time. Wait at least \_\_ hours before taking again. Do not take more than \_\_ (appropriate dosage form) in one day.

To further accommodate patients who are not able to understand the information in English, the Board is requiring that interpretive services in the patient's language be available. The interpreter may be available on the phone or in-person.<sup>20</sup> The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency to help them understand the information on the label. Also, there is consideration of also requiring that the direction wording on the label be available in the language the patient understands. The Board shall publish on its Web site translation of the directions for use listed above into at least five languages other than English in order to facilitate the use of such a service by California pharmacies.<sup>21</sup> More translation opportunities for other languages will be made available in the future by the Board through both telephone and Web site arrangements.

#### ***WHAT EXPIRATION DATES MAY BE USED ON A PRESCRIPTION LABEL?***

As a general rule, the dispensing pharmacist may either use the exact expiration date imprinted on the drug manufacturer's container, or a one year expiration date

from the date the drug is dispensed unless the manufacturer's date is earlier.<sup>22</sup>

Besides the manufacturer's expiration date or the one year from date of filling expiration date, the pharmacist may also use a reasonable expiration date that might be less than the year. As an example, certain drugs might run the risk of becoming contaminated after a short period of time of usage, such as topical nose drops or topical ophthalmological products, and might warrant a shorter than one year expiration date. Or an oral antibiotic that should be taken over a ten day period might also have an expiration period shorter than a year.

Therefore, in accordance with standards set for the use of expiration dates, a date different than the manufacturer's expiration date as part of the label affixed to a dispensed medication should "be based on the pharmacist's professional judgment and should take into account the nature of the drug, the container in which it is packaged, the expected storage conditions to which the drug may be exposed, and the expected length of time for the course of therapy."<sup>23</sup>

Expiration dates for extemporaneous unit dose packaging, compounding preparations for a prescriber's office use or for a patient, and parenteral solution preparations fall under different criteria and are discussed later on in this chapter. Generally, the expiration dates on these products are not to exceed one year for extemporaneous unit dose packaging, or six months for compounded products.<sup>24</sup>

Also refer to Chapter 4 where more is discussed about expiration dates under the section entitled, "*What Expiration Dates Can Appear On A Prescription?*"

### ***ARE THERE REFILL LIMITS ON A PRESCRIPTION WITH A "PRN REFILL" DESIGNATION?***

Under a State Attorney General Opinion, all nonscheduled prescriptions containing a "*prn refill*" designation may be refilled, where appropriate and reasonable, within one year or less of the date on the prescription without contacting the prescriber. In addition, no prescription for a controlled substance may be designated "refillable as needed."<sup>25</sup>

### ***WHAT INFORMATION MUST BE RECORDED EVERY TIME A PRESCRIPTION IS REFILLED?***

Assuming that the prescription requested to be refilled has allowable refills, then the pharmacist must maintain specific information on that prescription. The following information is required by law to be recorded in a readily retrievable manner:<sup>26</sup>

- The date dispensed.
- The name or initials of the dispensing pharmacist. All prescriptions refilled by an intern pharmacist must also be initialed by the supervising pharmacist before being dispensed.
- The quantity dispensed, if different from the original quantity dispensed as shown on the face of the prescription.
- If a generic drug or device is dispensed different from the generic drug or device originally or previously dispensed, the manufacturer's name or trade name for the new generic product shall be recorded.
- If no further refills are allowed on the prescription, and the pharmacist contacts the prescriber's office for additional refills, then the pharmacist or intern pharmacist must record the name of the party authorizing those refills, in addition to the number of new refills authorized and the date.

- A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, or if the prescription is over a year old for nonscheduled controlled substance prescriptions, or beyond the 5 refills or 120 days for refills on a schedule controlled substance prescription.

### ***OTHER DOCUMENTATION AND RECORDS WHICH MUST BE KEPT BY THE PHARMACY***

#### ***1. The Patient Drug Profile***

Does a pharmacy have to keep a patient medication profile on every patient that comes in to have a prescription filled? While the law does require that a pharmacy keep patient medication profile records on its patients, it does allow for an exception. The only case where the pharmacy does not have to keep a medication profile record on a patient is where the pharmacist has a “reasonable” belief that the patient will not continue to obtain prescription medications from that pharmacy.<sup>27</sup>

Here, the word “reasonable” is applied to a pharmacy practice situation. In a legal sense, the term “reasonable” involves an objective standard. It means “how the average prudent pharmacist would act under a similar circumstance when receiving a prescription from a patient.” Would he or she prepare a medication profile or not? Thus, the response is really a judgment call. Obviously, if the pharmacist senses that the patient with the prescription is a one-time encounter and will never return again, a medication profile on this patient is probably not of consequence and need not be prepared. This is probably how the “average prudent pharmacist would act under a similar circumstance.”

In the preparation of a patient medication profile, the profile should be easily retrievable and furnish the following information:<sup>28</sup>

- The patient's full name and address, telephone number, date of birth (or age), and gender.
- The name, strength, dosage form, route of administration, quantity, and directions for use for all drugs dispensed.
- The prescriber's name and, where appropriate, his or her license number, DEA registration number, or other unique identifier such as the type of prescriber.
- The date when a drug was first dispensed or refilled.
- The prescription number for each prescription.
- The name or initials of the dispensing pharmacist.
- The brand name of the drug or device; or, if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label.
- Any patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.
- Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

Each patient medication profile record that is created must be kept in the pharmacy's active files for at least one year from the date when the last prescription was filled.<sup>29</sup>

Furthermore, upon each subsequent filling or refilling of a prescription for a patient, a pharmacist shall review a patient's drug therapy and medication record using the patient medication profile created for that patient. Such review shall include screening for potential severe drug therapy problems.<sup>30</sup>

## 2. The "Faxed" Prescription as a Pharmacy Document

"Faxing" technology has provided a means of communicating prescription information as noted previously in this chapter. The faxed-prescriber signed prescription, especially for a non-scheduled controlled



substance medication is acceptable as a hard copy to be filed after filling as noted in the following code:

*CA. BUS. & PROF. CODES, SEC. 4040[c]*

“Electronic transmission prescription includes both image and data prescriptions. Electronic image transmission prescription means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber...”<sup>31</sup>

The above ruling also allows PA’s, NP’s, CNM’s, and NDs acting pursuant to a prescriber’s authorized protocol to forward prescriptions by electronic transmission, which includes faxing, to pharmacies.<sup>32</sup>

There are some important matters to consider when a prescription is faxed by any of the following methods: a) from the prescriber’s office to the pharmacy; b) from the patient to the pharmacy, and c) from one pharmacy to another pharmacy.

*Fax Transmission of a  
Prescription by a Prescriber*

Based upon the above, a faxed prescription for a non-scheduled controlled substance drug can legally be used to dispense drugs as long as all other requirements for written prescriptions (based on state laws) are satisfied.<sup>33</sup> The faxed prescription may also serve as the official prescription record to be maintained in the pharmacy’s files as noted above. Once a faxed prescription is received by the pharmacy from the prescriber’s office, it is the pharmacist’s responsibility to ensure that the transmitted document came directly from the prescriber and that all information required by law is present on the prescription. The faxed prescription must also contain the name of the party sending the prescription order by fax to the pharmacy.<sup>34</sup>

*Fax Transmission of a  
Prescription by a Patient*

Based upon the already discussed laws a faxed transmission of a prescription by a patient to a pharmacy shall not be recognized as a legitimate prescription and thus cannot be filled. If the pharmacist is uncertain of where the faxed prescription came from, it is his or her responsibility to ascertain this fact and act accordingly. Under this circumstance, the pharmacist must either obtain the original written prescription or receive it orally from the prescriber's office, committing it to writing or electronic storage immediately as required by law, before the prescription medication can be dispensed to the patient. In any event, the pharmacist should ultimately acquire the original prescription from the patient.

*Fax Transmission of a  
Prescription Between Pharmacies*

A pharmacist may transfer prescriptions for refill purposes by fax to other pharmacies for Schedule III, IV, or V controlled substances (only a one time transfer for Schedule III, IV, or V controlled substances), as well as for nonscheduled drugs (the transfer for non-scheduled controlled substance prescriptions can be made for as many times as there are refills).<sup>35</sup> The faxed document is to be treated as a telephonic order and is subject to the provisions stated in Section 1717[e] of Title 16, California Code of Regulations. (See the section entitled, *3. Documentation Involving The Transfer Of Prescription Refills Between Pharmacies* for more details regarding the transferring of both non-scheduled controlled substance prescriptions and schedule controlled prescriptions between pharmacies that immediately follows next within this Chapter.)

### 3. Documentation Involving the Transfer of Prescription Refills between Pharmacies

A pharmacist may transfer prescriptions containing refills for both nonscheduled drugs and Schedule III, IV, or V controlled substances.<sup>36</sup>

#### Transfer of Non-Scheduled Drug Prescriptions Between Pharmacies

Nonscheduled drug prescriptions having several refills may be transferred by either the pharmacist or pharmacist intern only to other pharmacies as many times as there are refills.<sup>37</sup> In other words, if a prescription for Drug "A" (a nonscheduled drug) allows 9 refills after being filled and refilled one time at Pharmacy XYZ, the remaining refills may be transferred to Pharmacy ABC per the patient's request. In so doing, Pharmacy XYZ must "void" all remaining refills. If there are 9 refills remaining on the prescription now at Pharmacy ABC and ABC refills the prescription one time, the patient can still continue to transfer the refills to another pharmacy, either to Pharmacy LMN or back to the original pharmacy, Pharmacy XYZ. This pattern may continue until all the refills for the drug order are used up. This of course may be done without contacting the prescriber. Keep six important facts in mind:<sup>38</sup>

- The multiple transfer only applies to nonscheduled drugs.
- Each time the remaining refills are transferred to another pharmacy, the transferring pharmacy must void all of the remaining refills noted on the prescription record by writing "void" across the prescription. No future refills may be assigned to this "voided" prescription.
- The sending pharmacy must place the name and address of the receiving pharmacy on its voided

prescription, also the date the transfer is requested, as well as the name of the pharmacist or pharmacist intern requesting the transfer.

- The receiving pharmacy must have the following information on the new prepared prescription being transferred:
  - Name and address of the sending pharmacy.
  - Name of the pharmacist or pharmacist intern transferring the prescription.
  - The number of remaining refills transferred.
  - The prescription number from the sending pharmacy.
  - The original date the prescription was written, the date of the last refill, and the date the prescription was transferred.
  - An indication on the prescription that it has been transferred.
- The pharmacy must prepare a new prescription each time they receive a prescription transfer from another pharmacy, even if they have the prescription on record as a result of having once transferred it to another pharmacy.
- The prescription can only be refilled within the period of a year from the time it was written regardless of the number of remaining refills. The prescriber must otherwise be contacted for further refills, and a new prescription is to be prepared.

**Transfer of Scheduled III, IV, or V Controlled Substance Drug Prescriptions Between Pharmacies**

Prescriptions containing refills for Schedule III, IV, and V controlled substances **may only be transferred once.**<sup>39</sup> When the transfer occurs, the receiving pharmacy must write on the face of the prescription that it is “*transferred*,” while the sending pharmacy must write “*void*” across the face of the originally filled prescription. The transferring of the

prescription must be communicated directly between two licensed pharmacists or pharmacist-interns.<sup>40</sup>

The transferring pharmacist must do the following:<sup>41</sup>

- Write the word "Void" on the face of the invalidated prescription.
- Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.
- Record the date of the transfer and the name of the pharmacist transferring the information.

The receiving pharmacy must do or have the following information:<sup>42</sup>

- The pharmacist or pharmacist intern must reduce the prescription to writing, initial the prescription, and indicate the date received.
- The word "transfer" must be written on the face of the prescription.
- The date of issuance of the original prescription must be noted.
- The original number of refills authorized on the original prescription must be noted.
- The date of the original dispensing of the prescription must be noted which may be different from the date of issuance of the prescription.
- The number of valid refills remaining and the date(s) and locations of previous refill(s).
- The pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.
- The name of the pharmacist who transferred the prescription.



The receiving pharmacy may fill the remaining refills according to the law pertaining to controlled substances, while the pharmacy that transferred the refills must call the prescriber for approval in order to dispense the scheduled drug on any subsequent refill request made by the patient.

#### 4. Records of Drug Selling, Buying, Lending, or Borrowing Between Pharmacies

A pharmacy that either lends drugs to another pharmacy or borrows drugs from another pharmacy shall be responsible for keeping records of such lending or borrowing. This also applies to all purchases and sales of prescription drugs or devices between pharmacies. The record to be kept must simply contain the name of the drug or device lent, sold, borrowed, or purchased, and the date the transfer took place.<sup>43</sup> Failure to keep such records exposes the pharmacist-in-charge to the risk of being charged with a misdemeanor.<sup>44</sup>

Scheduled II controlled substance transfers (involving a sale, lending, purchase or borrowing) between pharmacies must be pursuant to the execution of a DEA Form 222 (See Chapt. 13 under the Section entitled, “*May DEA Form 222 Be Used For The Return To The Supplier Or Sale To Other Pharmacies Of Schedule II Drugs?*”).<sup>45</sup>

The records for buy-sell or borrow-lend arrangements between pharmacies must be kept at the pharmacy for 3 years.<sup>46</sup>

#### 5. Records Concerning the Furnishing of Drugs During a State of Emergency

A registered pharmacist acting in “good faith” and in the best interest of the patient may furnish prescription drugs or devices in “reasonable” quantities during a declared state of emergency.<sup>47</sup> A patient who is in need of a prescription drug during a declared state of emergency need

not be a patient at the pharmacy he or she is seeking help from.

States of emergency may include such events as an earthquake, flood, mudslide, bombing, nuclear attack, acts of terrorism, or other extensive disastrous acts of God or by man. A declared state of emergency in order to be recognized as such must be announced by a federal or state official having the authority of declaring that state of emergency.

The types of medications that will be given out in the event of a state of emergency will be those drugs or devices that the patient may have already received, where it is known or where there is sufficient or reasonable evidence that the patient needs and has been getting a particular drug or device (e.g. evidence such as a prescription vial label with the name, strength, and directions of the drug on it; and evidence that the person is the true party in need of the prescription medication(s) [e.g. a driver's license containing the name, address and photo of the person named on the prescription label]).

Records for providing patients with prescription drugs during a declared state of emergency where no past records are available are to be kept on a separate ledger (writing out separate prescriptions for any drugs given out to patients for this emergency purpose is not required). Entry onto the ledger shall contain the following information:<sup>48</sup>

- The name and address of the person to whom the drug or device is furnished.
- The date the drug or device is furnished.
- The name, strength, and quantity of the drug or device furnished.
- The prescriber's name and where he or she can be contacted.

All information concerning the furnishing of drugs or devices under an emergency circumstance shall be communicated to the patient's physician as soon as possible. Furthermore, in a state of emergency situation, a person may

possess a dangerous drug or device that has been furnished without a prescription.<sup>49</sup>

The use of Mobile Pharmacies during a declared state of emergency: During such a declared state of emergency, the Board shall allow for the placement of mobile pharmacy units to operate in impacted areas provided the following conditions are met:<sup>50</sup>

- The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing.
- The mobile pharmacy retains records of dispensing prescription medications and devices.
- A licensed pharmacist is on the premises and the mobile pharmacy is under the control and management of a pharmacist while the drugs and devices are being dispensed.
- Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.
- The mobile pharmacy is located within the declared or affected emergency area.
- The mobile pharmacy ceases the provision of services within 48 hours following the termination of the declared emergency.

6. Records Required in the Preparation of Extemporaneous Unit Dose Packaging

The U.S. Pharmacopeia and National Formulary states that anytime a pharmacy prepares extemporaneous unit dose packaging, records must be kept, usually in the form of a ledger, which contains the following information:<sup>51</sup>

- The date when an extemporaneous supply of unit dose medications is prepared by the pharmacy.
- The party preparing the extemporaneous supply of unit dose medications, and the initials of the supervising pharmacist.
- The lot number or lot numbers of the drug used for the unit dose preparation, and the amount of drug used from

each lot number batch, along with the expiration date(s) on the manufacturer's label.

- The name and strength of the drug used.
- The manufacturer's name.
- The expiration date that will be assigned to the unit dose packages that shall not exceed one year. An earlier than one year date is to be used if the expiration date on the manufacturer's label is less than a year.

In addition to the above, the extemporaneous unit dose drug label must contain the following information:<sup>52</sup>

- The name and strength of the drug.
- The dosage form
- The lot number of the drug.
- The expiration of the drug: One year, or less if the expiration date on the manufacturer's package is less than one year.
- Individual extemporaneous unit doses and the attached labeling prepared by a centralized hospital packaging pharmacy to be administered to inpatients within its own general acute care hospital settings where there is common ownership and the hospitals are within 75 miles of each other, will require barcoding on each label in order that prior to administration of the unit dose packaged drug to a patient, the person administering the drug will scan the drug's bar code to ensure the drug complies with the medical chart record before administering the drug. This law was adopted in late September of 2012 and will go into effect in 2013. Further required is a specialty license to be issued by the Board to have a centralized hospital packaging pharmacy operation.<sup>53</sup>

#### 7. Notice To The Consumer On The Use Of Common Prescription Files Between Pharmacies

Since many chain pharmacy operations already have a shared computerized prescription file system making it

convenient for patients to pick up their prescriptions at different pharmacies within the chain, such pharmacies are allowed to establish and use a common electronic file system to maintain prescription and dispensing information.<sup>54</sup> Further requirements stated in the law for common electronic files are the following:

- For controlled substances: To the extent permitted by federal law, two or more pharmacies may establish and use a common electronic file prescription and dispensing information. Note according to federal law Schedule II controlled substances may not be transferred, and Schedule III, IV, and V controlled substance prescriptions can be transferred one time only.<sup>55</sup>
- All common electronic files must contain complete and accurate records of each prescription and refill dispensed.
- Common electronic files shall not permit disclosure of confidential medical information except as authorized by the Confidentiality of Medical Information Act.<sup>56</sup>
- Pharmacies maintaining a common electronic file shall develop and implement written policies and procedures designed to prevent the unauthorized disclosure of confidential medical information.<sup>57</sup>

Prior to March 2007 it was required that any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a conspicuous place in the pharmacy area that the pharmacy shares its prescription file information with other pharmacies. Given this written notice, the consumer could request in writing that his or her prescription records not be available to other pharmacies in this common file system. This requirement of posting notice was repealed as of March 25, 2007, and is no longer law.



***MAY A PHARMACY KEEP ITS PRESCRIPTION RECORDS  
IN AN ELECTRONIC FILING SYSTEM WITHOUT  
REDUCING SUCH RECORDS TO WRITING?***

A pharmacy that receives an electronic transmission of a prescription is no longer required to reduce the prescription to writing as long as the pharmacy is able to immediately produce a hard copy on request.<sup>58</sup> Further, it is required that the pharmacy's computer system be programmed to inhibit any changes to, or deletions of information electronically stored, unless authorized by the pharmacist.<sup>59</sup>

***THE NATURE OF THE SELF ASSESSMENT SURVEY  
TO BE COMPLETED BY EACH PHARMACY***

Every pharmacy in California will be responsible, under the direction of the pharmacist-in-charge, to respond to a general self-assessment survey to aid the pharmacy in reviewing the pharmacy's compliance with both federal and state pharmacy-related laws. The general self-assessment survey was made available at the beginning of 1999 and must be completed before July 1<sup>st</sup> of every odd-numbered year for both community and hospital pharmacy operations.<sup>60</sup>

California law now requires that special self-assessment surveys be done in addition to the general pharmacy survey if a community pharmacy engages in non-sterile drug compounding, and a separate self-assessment be done if the community pharmacy is licensed to perform sterile compounding.<sup>61</sup> Thus, the pharmacist-in-charge must complete either two or three self assessment surveys every two years (the third survey being for sterile compounding if the community pharmacy has a California issued license to perform sterile compounding), prior to July 1<sup>st</sup> of every odd-numbered year.<sup>62</sup>

A new self-assessment survey (includes all of the surveys noted above) must be completed within 30 days

whenever a new pharmacy permit has been issued or there is a change in the pharmacist-in-charge.<sup>63</sup> Among the compliance issues to be reviewed in the self-assessment are the facility's condition and security, nature of drug stock, posting of certificates and notices, pharmacist-in-charge responsibilities, pharmacist-intern activities, pharmacy technician tasks, controlled substance prescription dispensing and records, prescription labeling and dispensing practices, prescription refill and transfer practices, methods of ensuring patient confidentiality, prescription drug compounding and repackaging practices, and electronic transmission of prescription procedures.<sup>64</sup>

While the self-assessment surveys must be undertaken every two years, the pharmacy must retain the filled-out surveys at the pharmacy for a period of 3 years.<sup>65</sup>

### ***MAY A PHARMACY REPACKAGE A PREVIOUSLY DISPENSED MEDICATION FOR A PATIENT?***

A pharmacy may, at a patient's request, repackage a drug previously dispensed to the patient.<sup>66</sup> Any pharmacy providing repackaging services shall have policies and procedures for the performing of this service, and shall label the repackaged prescription container with the following:<sup>67</sup>

- All information required under the prescription labeling provision of the Calif. Bus. & Prof. Codes, Sec. 4076.
- The name and address of the pharmacy repackaging the drug and the name and address of the pharmacy that initially dispensed the drug to the patient if such an arrangement was made.

An example where a patient has a prescription initially dispensed, and because of some trouble in having easy access to the product wants to have it repackaged differently, is often the case where tablets are in a unit dose

blister package. In order to provide easy access to the medication, the pharmacist can remove each of the doses from the individual packages and place them in a properly labeled prescription vial.

### ***MAJOR POLICIES AND PROCEDURES REQUIRED TO BE AVAILABLE AS PHARMACY OPERATIONAL DOCUMENTS***

A pharmacy is responsible for having the following *Policies and Procedures* available in writing and present in the pharmacy as required by law:

- Pharmacist involvement in the provision of various patient care services that fall within the “extended scope of practice” standards. Many of these programs require mandatory training that should also be noted in the policy and procedures for this category and prescriber directed protocols.<sup>68</sup>
- Ordering or performing routine drug therapy-related patient assessment procedures.
- Ordering drug therapy-related laboratory tests.
- Administering drugs and biological by injection.
- Initiating or adjusting the drug regimen of a patient.
- Emergency Contraception Drug Therapy.
- Skin punctures in the course of performing routine patient assessment procedures
- The repackaging of previously dispensed medications.<sup>69</sup>
- The provision of prescription drugs during a declared state of emergency.<sup>70</sup>
- The provision of discharge medications and consultation to a hospitalized patient.<sup>71</sup>
- Prescription container labeling requirements.<sup>72</sup>
- Dealing with drug theft, diversion, illegal use, or chemical, physical or mental impairment of a licensee

- that affects his or her ability to practice in a pharmacy.<sup>73</sup>
- Providing emergency drugs to a licensed health care facility.<sup>74</sup>
  - Quality Assurance program involving medication error reporting.<sup>75</sup>
  - Use of Automated medication delivery device systems.<sup>76</sup>
  - Pharmacy operations during the temporary absence of a pharmacist.<sup>77</sup>
  - Entry of information into an automated data processing system, or a manual record system.<sup>78</sup>
  - Use of a common electronic file system, and means of preventing unauthorized disclosure of confidential medical information.<sup>79</sup>
  - Protocols for the provision of emergency contraception.<sup>80</sup>
  - Sterile Injectable Compounding, if done by pharmacy.<sup>81</sup>
  - Meeting General Compounding Requirements By A Pharmacy.<sup>82</sup>
  - Furnishing prescription drugs to Home Health Agencies and Licensed Hospices.<sup>83</sup>
  - Pharmacy Technician Duties, Responsibilities, and Evaluation Standards.<sup>84</sup>

The above items represent the bulk of required policy and procedures that should be present in writing in a pharmacy. There are many other circumstances where policies and procedures, that are not required by law, would be appropriate to standardize operational situations so that the pharmacy staff would handle such situations in the same manner each time they present themselves, and will hopefully reduce confusion among the pharmacy staff members and further reduce medication errors.

**REFERENCES TO CHAPTER 7**

1. Calif. Bus. & Prof. Codes, Sec. 4040[a]
2. *Ibid.* at Sec. 4070[a], Calif. Health & Safety Code, Secs. 11164[b][1] & 11167
3. Calif. Bus. & Prof. Code, Sec. 4040[c] & Title 16 Calif. Code of Regs., Sec. 1717.4[e]
4. Calif. Bus. & Prof. Code, Sec. 4070[b]
5. *Ibid.* at Sec. 4070[a] & Title 16, Calif. Code of Regs., Sec. 1717.4[c]
6. Calif. Bus. & Prof. Codes, Sec. 4040[d]
7. Title 16, Calif. Code of Regs., Sec. 1761[a]
8. *Ibid.* at Sec. 1761[b]
9. *Ibid.* at Sec. 1717[b]
10. *Ibid.* at Sec. 1717[b][3]
11. *Ibid.* at Sec. 1717[b][4]
12. *Ibid.* at Sec. 1717[c]
13. Calif. Bus. & Prof. Code, Sec. 4076[a]
14. *Ibid.* at Sec. 4076[a][11][A]
15. Title 16, Calif. Code of Regs., Secs. 1717[b][1] & 1793.7[a]
16. *Ibid.* at Sec. 1735.3[a][8]
17. Calif. Bus. & Prof. Code, Sec. 4076.5[c]
18. Title 16, Calif. Code of Regs., Sec. 1707.5[a][1][2]
19. *Ibid.* at Sec. 1707.5[a][4]
20. *Ibid.* at Sec. 1707.5[b]
21. *Ibid.* at Sec. 1707.5[b][d]
22. Calif. Bus. & Prof. Codes, Sec. 4076[a][9]. Also, *The Script* (Publication of the California State Board of Pharmacy), Jan. 2002 Edition, p. 9
23. *The Script* (Publication of the California State Board of Pharmacy), Feb. 1997 Edition, p. 13
24. United States Pharmacopeia, 35th Rev., and The National Formulary, 30<sup>th</sup> Ed. (USP35/NF30), Aug.1, 2012 to Nov. 30, 2012, Section 10.40.100 “*Expiration Date and Beyond-Use Date*,” and Title 16, Calif. Code of Regs., Sec. 1735.2[h].
25. Calif. Bus. & Prof. Code, Sec. 4063
26. Title 16, Calif. Code of Regs. Sec. 1717[b]
27. *Ibid.* at Sec. 1707.1[a]



28. *Ibid.* at Sec. 1707.1[a][1]
29. *Ibid.* at Sec. 1707.1[a][2]
30. *Ibid.* at Sec. 1707.3
31. Calif. Bus. & Prof. Code, Sec. 4040[c]
32. *Ibid.* at Sec. 4040[a][2]
33. *Ibid.* at Sec. 4070[b]
34. *Ibid.* at Secs. 4071 & 4072[a]
35. Title 21, Code of Fed. Regs., Sec. 1306.25 and Title 16, Calif. Code of Regs., Sec. 1717[e]
36. Title 16, Calif. Code of Regs., Sec. 1717[e]
37. *Ibid.* at Sec. 1717[e]
38. *Ibid.* at Sec. 1717[e]
39. Title 21, Code of Fed. Regs. (CFR), Sec. 1306.25[a]
40. *Ibid.* at Sec. 1306.25[b][1]
41. *Ibid.* at Sec. 1306.25[b][2]
42. *Ibid.* at Sec. 1306.25[b][3]
43. Calif. Bus. & Prof. Code, Sec. 4081[a][b][c]
44. *Ibid.* at Sec. 4332
45. Title 21, Code of Fed. Regs. (CFR), Sec. 1307.11 & 1307.12[a]
46. Calif. Bus. & Prof. Code, Sec. 4081[a]
47. *Ibid.* at Sec. 4062[a]
48. *Ibid.* at Sec. 4062[a]
49. *Ibid.* at Sec. 4062[a]
50. *Ibid.* at Sec. 4062[c]
51. The United States Pharmacopeia, USP 27, Sec. 1146: *Packaging Practice – Repackaging a Single Solid Oral Drug Product Into a Unit-Dose Container.*
52. The United States Pharmacopeia, USP 27, Sec. 1146: *Packaging Practice – Repackaging a Single Solid Oral Drug Product Into a Unit-Dose Container.*
53. Calif. Bus. & Prof. Code, Secs. 4029, 4128, 4128.2, 4128.3, 4128.4, and 4128.5
54. Title 16, Calif. Code of Regs., Sec. 1717.1
55. Title 21 CFR, Sec. 1306.25[a]
56. Calif. Civil Codes, Sec. 56
57. Title 16, Calif. Code of Regs., Sec. 1717.1[e]
58. Calif. Bus. & Prof. Code, Sec. 4070[b]
59. *Ibid.* at Sec. 4070[c]

60. Title 16, Calif. Code of Regs., Sec. 1715[a]
61. *Ibid.* at Sec. 1735.2[j]
62. *Ibid.* at Sec. 1735.2[j]
63. *Ibid.* at Sec. 1715[b]
64. *Ibid.* at Sec. 1715[c]
65. *Ibid.* at Sec. 1715[d]
66. Calif. Bus. & Prof. Code, Sec. 4052.7[a]
67. *Ibid.* at Sec. 4052.7[b]
68. *Ibid.* at Secs. 4052.1 & 4052.5
69. *Ibid.* at Sec. 4052.7
70. *Ibid.* at Sec. 4062
71. *Ibid.* at Sec. 4074
72. *Ibid.* at Sec. 4076
73. *Ibid.* at Sec. 4104
74. *Ibid.* at Sec. 4119
75. Title 16, Calif. Code of Regs., Sec. 1711
76. *Ibid.* at Sec. 1713[d][e][f] & Calif. Health & Safety Code, Sec. 126.6
77. Title 16, Calif. Code of Regs., Sec. 1714.1
78. *Ibid.* at Sec. 1717[f]
79. *Ibid.* at Sec. 1717.1[e]
80. *Ibid.* at Sec. 1746
81. *Ibid.* at Secs. 1751-1751.8
82. *Ibid.* at Secs. 1735-1735.8
83. *Ibid.* at Sec. 1751.11
84. *Ibid.* at Secs. 1793-1793.8

## CHAPTER 8

# PATIENT ORAL AND WRITTEN COMMUNICATIONS

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**WHAT INFORMATION IS THE PHARMACIST  
REQUIRED TO GIVE TO THE PATIENT DURING  
A DRUG CONSULTATION SESSION?**

Perhaps one of the most significant pharmacy laws to be established within the last 22 years is the *patient drug consultation regulation*. This regulation mandates that a pharmacist shall provide *oral* consultation to his or her patient or the patient's agent in all patient care settings where the patient is receiving or being discharged with a new prescription medication. This oral consultation shall be rendered under the following conditions:<sup>1</sup>

- Whenever the prescription drug has not previously been dispensed by that pharmacy to the patient in the same dosage form, strength or with the same written directions. Therefore, whenever any new prescription is dispensed or where there is a modification of an existing prescription, an oral consultation must be provided by the pharmacist. The pharmacy intern may also provide oral consultation to the patient or patient's representative about the medications dispensed, even though this is not stated in the exact language of the regulation. Remember that a pharmacy intern can perform any pharmacy-related activity that a pharmacist does (except possess a key to the pharmacy), as long as the pharmacy-related activity is performed under the direct supervision of the pharmacist.
- Whenever the patient requests an oral consultation on his or her drugs. This means that the patient is entitled to a consultation, even if the prescription is not new and is a refill, as long as the patient makes the request.
- Whenever the pharmacist deems it necessary to provide such a consultation, regardless of whether the drug is a new or a refill prescription.

Presently, the California Codes include much of the federal language mandated in Section 4401 of the Omnibus

Budget Reconciliation Act of 1990 (referred to as "OBRA '90") that was originally drafted for Medicaid prescription recipients. The California Code of Regulations now requires that the following information be provided orally by the pharmacist for each patient receiving a new prescription:<sup>2</sup>

- The oral consultation shall include at least the following:
  - Directions for use and storage.
  - Information supporting the importance of compliance with the directions for the use of the drug.
  - Precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.
- When the pharmacist deems appropriate, oral consultation shall also include:
  - Name and description of the medication.
  - Route of administration and dosage form.
  - Dosage and duration of therapy.
  - Any special directions for use and storage.
  - Precautions for drug preparation and administration by the patient, including techniques for self-monitoring the drug therapy.
  - Prescription refill information.
  - Therapeutic contraindications. Methods for avoiding common severe side or adverse effects or known interactions with known nonprescription medications.
  - Action to be taken if a side or adverse effect or interaction or therapeutic contraindication should be present or occur.
  - Action to be taken in the event of a missed dose.
- Furthermore, the pharmacist is obliged to review, prior to the dispensing of the medication, the patient's drug therapy and medication record. Such review shall serve as a method of screening for severe potential drug therapy problems.<sup>3</sup> See *Chapter 7* for a



discussion of the “*Patient Drug Profile*.” This review also serves as a means for screening for:

- Therapeutic duplication.
- Drug-disease contraindications.
- Drug-drug interactions.
- Incorrect drug dosage or duration of drug therapy.
- Drug-allergy interactions.
- Clinical abuse or misuse.

Keep in mind that the only two circumstances where a pharmacist does not have to provide an oral consultation to the patient are: 1) where the prescription has been previously filled as written, or 2) where the patient refuses such a consultation.

Because of the somewhat limited directive of the “Patient Consultation” regulation, the California State Board of Pharmacy has developed some guidelines both to help interpret this regulation and to answer some of the more common questions the regulation poses. The following are some questions and responses that the Board felt needed to be addressed:<sup>4</sup>

*Must a Pharmacist Consult with a  
Patient who is being Discharged  
with Medications?*

Originally, the board provided this answer: “Generally, the answer is yes, the consultation must occur. However, the patient can specifically designate someone else, such as a family member or a nurse, to receive the consultation from the pharmacist on the patient’s behalf.”

A more contemporary answer is now provided in Section 4074[d] of the Calif. Bus. & Prof. Codes, which now requires the following: “A health care facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each medication given at the time of discharge.”

The oral discharge consultation shall include the same information stated above under the

mandatory consultation regulation and "shall be given by a pharmacist or registered nurse, unless already provided by a physician." The written policy shall address the conditions under which the discharged patient must be consulted about his or her medications.<sup>5</sup>

Any patient discharge medication consultation provided should be noted in the patient's medical record. If the patient is simply given the prescription forms upon discharge and not the medication from the prescription, no consultation need be provided upon the discharge since the prescriptions will presumably be filled later at an outpatient pharmacy. Preliminary information may be provided to the patient by the hospital staff, but the dispensing pharmacist is still responsible for consulting with the patient.

**Why is Consultation Not Required  
for All Inpatient Medications?**

"In a health care facility, the staff ensures that patients receive their medication. Staff also monitors the patient's progress. However, upon discharge, the patient may no longer be monitored and it is important that he or she be knowledgeable about the medication at the time of discharge."

**Why Must the Consultation be Oral?**

"Written materials may be provided as a supplement to, but not as a substitute for, oral consultation. Written information may provide meaningful direction to a patient but often fails to answer the patient's specific questions."

**What if the Patient Cannot Understand English  
or has Another Type of Disability that Makes It Difficult  
for Him or Her to Understand the  
Oral Consultation?**

"The Board recognizes that language barriers do exist, but the pharmacist must make a *good faith effort* to consult with the patient. If the pharmacist attempts to provide consultation, but the patient does not understand English, or is hearing-impaired, and the patient's agent is unavailable, the Board will view

the situation as a good faith effort to comply with the regulation. The pharmacist should also exercise his or her best efforts to provide consultation or to contact a competent representative for an incompetent patient or an unaccompanied minor. The pharmacist should, for his or her own protection, document the inability to provide consultation, including the reasons why and what actions were taken. If oral consultation is impossible, then written material could be provided."

If a particular non-English speaking language is common to a pharmacy's operation, then a standard may arguably exist to provide consultations in that particular language for accommodation purposes. Recent law requires that interpretative language services (usually by telephone) now be available and written policies and procedures be established.<sup>6</sup>

*Is the Pharmacist Required to Document  
the Consultation in Some Way?*

"No, but many pharmacies may want to establish procedures that will indicate a patient consultation occurred, and who performed it."

*How will the Board Enforce  
this Regulation?*

"During an inspection, the Board's inspectors will observe whether a consultation occurs when required, and whether the pharmacy has attempted to present an environment conducive to providing consultation, and may review the patient medication profiles. The Board will also investigate complaints indicating that a pharmacy is not providing profiles as required."

*Pharmacist Intern Provides the  
Oral Consultation*

A pharmacist intern may provide the patient medication consultation. However, if the pharmacist intern consults orally with the patient about his or her new prescription medications, the pharmacist must physically be within hearing distance of the pharmacist intern.

***WHAT CONSULTATION REQUIREMENTS  
EXIST WHEN A PRESCRIPTION DRUG IS  
MAILED OR DELIVERED?***

When a prescription is sent to a mail order pharmacy, that pharmacy must still provide some form of access to a patient medication consultation. However, according to the codes, the Board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. In such cases the pharmacy shall ensure that the patient receives:<sup>7</sup>

- Written notice of his or her right to request consultation, and
- A telephone number that the patient can call in order to obtain oral consultation from a pharmacist who has ready access to the patient's medication record. If the pharmacy operation is primarily a mail order pharmacy, an "800" phone number may be provided. If the pharmacy is not designated as a mail order operation, and only mails out prescriptions occasionally, then the regular pharmacy number must be made available to the patient advising the patient to call for prescription information only during the hours the pharmacy is open.

***WHAT KIND OF INFORMATION MUST BE  
PROVIDED TO CONSUMERS REGARDING  
A PHARMACY'S SERVICES?***

Every pharmacy must post in a conspicuous place a "*NOTICE TO CONSUMERS*" statement that presents information pertaining to prescription prices, the availability of generic drugs, and questions that the patient might wish to ask the pharmacist about his or her medications. Usually, the most "conspicuous" spot in which to place the "*NOTICE TO CONSUMERS*" is in the area where prescriptions are filled. The "*NOTICE*" itself must read as follows:<sup>8</sup>

*Notice to Consumers*

*At your request, this pharmacy shall provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.*

*Ask your pharmacist if a lower-cost generic drug is available to fill your prescription.*

*Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.*

*Before taking any medicine, talk to your pharmacist – be sure you know:*

- *What is the name of the medicine and what does it do?*
- *How and when do I take it – and for how long? What if I miss a dose?*
- *What are the possible side effects and what should I do if they occur?*
- *Will the new medicine work safely with other medicines and herbal supplements I am taking?*
- *What foods, drinks or activities should I avoid while taking this medicine?*

*Ask your pharmacist if you have additional questions.*

There is also a requirement that patients be advised by means of a posted notice in the pharmacy in a conspicuous place that there is a responsibility imposed upon the pharmacist and pharmacy to describe to the patient what responsibility the pharmacist has if: he or she refuses to fill a prescription due to an ethical or religious belief; the prescription drug is not in stock; or the patient is unable to pay for the prescription.<sup>9</sup> Further the notice is to describe a patient's rights concerning drugs and devices that are prescribed, and the right to have their prescriptions returned to them or transferred to another pharmacy if the pharmacy is unable to fill the prescription.

It is suggested that the above notices be incorporated together along with language interpretive services that are available to those who do not understand English, into a video presentation from a television monitor in the pharmacy area.<sup>10</sup>



***IS IT REQUIRED THAT PRICES OF  
SPECIFIC DRUGS BE POSTED?***

There is presently no requirement that the pharmacy must post prices of certain drugs for the consumer to see. However, the law does require that there is a written posting, in a conspicuous place, advising consumers of the availability of prescription price information that may be obtained from the pharmacist. An alternative to the notice posting is to provide the consumer directly with a written statement indicating that prescription price information may be obtained from the pharmacist.<sup>11</sup>

If prices are posted for public view, then the following guidelines should be adhered to:<sup>12</sup>

- The advertisement must not be a misrepresentation of fact.
- The retail price for a prescription drug shall state the quantity that price represents, and the strength and dosage form of the drug.
- The advertisement must state the exact dates during which the advertised price will be in effect.

***WHAT IS THE OBLIGATION OF THE PHARMACIST  
IN GIVING PRESCRIPTION PRICE INFORMATION TO  
A REQUESTING CUSTOMER?***

A pharmacist or pharmacist's employee shall give the current retail price for any drug sold at that pharmacy upon the request of a consumer.

If a consumer requests the price for more than 5 prescription drugs and does not have prescriptions available for all or some of those drugs, the pharmacist may act in any of the following ways:<sup>13</sup>

- The pharmacist may require that the consumer's request be in writing.

- The pharmacist shall respond to the written request within a reasonable time (10 days is considered a reasonable time) or that time period stated in the written request, whichever is later.
- The pharmacy may charge a reasonable fee for each prescription price quotation. The consumer must be informed of this charge before or when the prescription information is given to the pharmacist, and the charge is to be included in the price for the prescriptions if filled at the pharmacy where the request is made.
- A pharmacy shall not be required to respond to more than 3 requests from any one person or entity in a six-month period.

There are several situations in which the pharmacist is not obligated under the law to provide drug prices from a party requesting such information. Those situations involve the following:<sup>14</sup>

- The price for a controlled substance when it is a telephone request.
- A price request from a competitor.
- A price request from an out-of-state requester.

***WHAT ORAL OR WRITTEN INFORMATION MUST  
ACCOMPANY THE DISPENSED DRUG OTHER  
THAN THE AFFIXED LABEL  
CONTAINING DIRECTIONS FOR USE?***

There are two major forms of written materials, other than the label affixed to the drug container that provides the directions for use, that may be required by law or the manufacturer to accompany each prescription that is filled and dispensed. The two items of additional written information that are or may be required include the following:

- The use of auxiliary labels warning the patient about the hazards of taking the dispensed medication with alcohol

or while operating machinery if the medication can cause drowsiness (see the section below on *"The Use Of Auxiliary Prescription Labels"* for further discussion on this subject).<sup>15</sup>

- Provision of "Patient Medication Guides" are required by federal law to be provided to the patient upon receiving a prescription drug that has a such a "Guide." Approximately 500 prescription drugs require this "Medication Guide" to be provided to the patient each time the prescription is dispensed. Essentially these "Medication Guides" alert the patient to the risks versus the benefits of the drug, and what the patient should monitor and look out for while taking the drug.<sup>16</sup> Prescription drugs that do not have "Medication Guides" may have written information provided by the drug manufacturer as a patient drug insert that is expected to be given to the patient each time the drug is dispensed. While the provision of a manufacturer's patient information is not generally a requirement by law, but if such information is not passed on to the patient, and the patient is harmed because of not having such information, a civil suit brought by the patient against the pharmacy could be the outcome.

It is also important to recognize that pharmacies may generate written computer information for every drug that is dispensed. While this is generally not required by law, but is valuable in complementing the law-required oral consultation that must be given with the dispensing of a new drug to a patient. It is also important to note that computer generated drug information forms may not conform to the exact wording in a law-required "Patient Medication Guide." If that is the case, computerized medication forms that do not have the same language as the "Medication Guides" cannot serve as a substitute for the "Guides."

**A. Oral or Written Statement Advising Patient  
About Adverse Drug Reactions**

A patient receiving a prescription drug shall be informed by the pharmacist orally or in writing of any harmful effects of the drug.<sup>17</sup>

**B. The Use of Auxiliary Prescription Labels**

Most of the auxiliary labels that pharmacists place on the dispensed prescription vial in conjunction with the label containing the directions are placed upon the drug container as a matter of common sense to ensure that the patient correctly stores, uses, and obtains the maximum benefits from the drug. So, attached auxiliary labels such as "Shake Well," "Refrigerate," or "For External Use Only" are primarily ethical advisements that should be reinforced orally as part of the consultation requirement that ensures that the patient uses and stores the drug properly. Also, these requirements are generally supported by the drug manufacturer's written statements.

Auxiliary drug warning labels are required by law where 1) the drug may cause drowsiness, 2) may affect vision, 3) the drug when combined with alcohol may cause drowsiness or some other serious effect, or 4) the prescription drug is placed in a multiple-drug medication package (referred to as a "patient med pak").<sup>18</sup>

Several drugs or classes of drugs are listed in the regulations as products which, when taken systemically, either alone or in combination with alcohol, may impair a person's ability to drive a motor vehicle or operate machinery. Consequently the patient receiving such a drug must be informed in writing, orally, or both that "**THIS DRUG MAY CAUSE DROWSINESS WHEN TAKEN ALONE OR IN COMBINATION WITH ALCOHOL. OPERATION OF A MOTOR VEHICLE SHOULD BE AVOIDED WHILE TAKING THIS MEDICATION.**" (These exact words do not have to be used. Words that convey a message about the use of the drug, alone or with alcohol, and the danger in

operating a vehicle are sufficient.) These drugs or classes of drugs are:<sup>19</sup>

- Muscle relaxants.
- Analgesics with central nervous system depressant effects.
- Antipsychotic drugs including phenothiazines.
- Antidepressants.
- Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants, and antihypertensive agents with central nervous system depressant effects.
- All Schedule II, III, IV and V depressant or narcotic controlled substances prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.
- Anticholinergic agents and other drugs which may impair vision.
- Disulfiram and other drugs (e.g. chlorpropamide, metronidazole) which may cause a disulfiram-like reaction when taken with alcohol.
- Monoamine oxidase inhibitors.
- Nitrates.

If the drug is stored in a multiple-drug medication package ("patient med pak") the container must have affixed to it an auxiliary label stating "*store in a cool, dry place.*" By definition the "patient med pak" is a refillable prescription for a non-liquid oral product placed in a clean reusable container used by the same patient, and is to only contain no more than a one month supply.

Concerning controlled substances, the federal codes require that each prescription dispensed for a controlled substance be provided with not only written and/or oral information about the drug's causing drowsiness, but the following information (in the form of an auxiliary label) as well:<sup>20</sup>

***"CAUTION: FEDERAL LAW PROHIBITS THE  
TRANSFER OF THIS DRUG TO ANY PERSON  
OTHER THAN THE PATIENT FOR WHOM IT WAS  
PRESCRIBED."***



### *C. The Mandatory Patient Medication Guide*

Aside from the legal requirement that a patient receive a FDA Patient Medication Guide for those prescription drugs that have such "Guides," there still exists an older regulation regarding the provision of a Patient Medication Package Insert for a patient that is prescribed an estrogenic substance.<sup>21</sup> "Each estrogen drug product restricted to prescription distribution, including products containing estrogens in fixed combinations with other drugs, shall be dispensed to patients with a patient package insert containing information concerning the drug's benefits and risks."<sup>22</sup> Patient information pertaining to oral contraceptives that contain an estrogenic component must also have a statement concerning the effectiveness of the oral contraceptive in preventing pregnancy, along with a warning statement concerning the increased risks associated with cigarette smoking.<sup>23</sup> While the provision of "Patient Medication Guides" for some 500 prescription drugs and the "Patient Package Insert" for estrogenic substances is required by law, other Patient Package Inserts to be given to the patient are a requirement of the drug manufacturer.

### *WHAT ARE "BLACK BOX WARNINGS" AND THEIR SIGNIFICANCE*

A "Black Box Warning" (also referred to as a "Black Label" or "Prescription Boxed Warning") will appear on both the package inserts and Patient Medication Guides for specific prescription drugs that are capable of causing serious adverse effects. The FDA is requiring that prescribers and pharmacists make patients who take drugs with these special warnings be advised through consultation and written materials about the serious adverse effects that this class of prescription medications can cause. The hope intended from these warnings is to make the patient more aware and observant of the potential risk the drugs in this

category are capable of and what to do if a serious adverse effect is experienced.

Examples of “Black Box Warnings” are associated with the following prescription medications:<sup>24</sup>

- **Fluoroquinolone Antibiotics** – increase the risk of tendinitis and tendon rupture.
- **Diabetes Medications** – Avandia (rosiglitazone) can cause an increase risk of heart failure or heart attack in patients who have underlining heart disease.
- **Antidepressant Medications** – increase risk of suicidal ideation, especially in young adults ages 18 to 24 during beginning treatment (first one to two months).
- **Such drugs as Zoloft (sertraline), and Paxil (paroxetine), and other SSRIs** have been associated with this adverse effect of suicidal ideation.
- **Anticoagulant drugs (primarily warfarin)** – increase risk of excessive bleeding.
- **Certain Anti-Seizure Medications** – increase risk of suicidal behavior.
- **Sodium Phosphate Preparations**, especially those used in colonoscopy procedures for clearing the bowel, present an increase risk of kidney damage if not diluted properly.

There are a number of other drugs that have black box warnings, and it is of extreme importance that these warnings be carefully conveyed to patients, as well as monitored by both prescribers and pharmacists. California hospital pharmacies have over the last several years been highly scrutinized by various state agencies for not carefully monitoring patients on drugs that have Black Box warnings, and not developing or implementing policies and procedures that ensure that patients on these categories of drugs will be more closely followed.

***MUST A PHARMACY POST A NOTICE THAT IT  
SHARES AN ELECTRONIC FILE NETWORKING  
SYSTEM WITH OTHER PHARMACIES?***

“No,” is the answer to this question. Prior to March 2007 it was required that “any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a conspicuous place in the pharmacy area that can be read by prescription drug consumers.” This requirement was repealed as of March 25, 2007, and is no longer law.<sup>25</sup> The repealed regulation was stated in Title 16, Calif. Code of Regs., Sec. 1717.2

***MAY PHARMACISTS ADVERTISE THEIR  
SERVICES OR DRUG PRICES?***

Pharmacists and pharmacies may advertise their services and drug prices as long as such advertising conforms to specified standards.<sup>26</sup> It is incumbent upon the pharmacist not to falsely advertise or mislead the public as to drug prices or professional services. Truthful advertising regarding product prices and services must prevail regardless of the media used to provide such advertising. Furthermore, false or misleading advertising will be considered a misdemeanor whether done intentionally or negligently.<sup>27</sup> In general, a false or misleading statement or claim may include any of the following:<sup>28</sup>

- A misrepresentation of a material fact.
- A statement which misleads based on a failure to disclose a material fact.
- A statement which creates false or unjustified expectations of favorable results.
- Any statement concerning fees, other than a standard consultation fee or a range of fees for specific types of services, which fails to fully and specifically disclose all variables and other material factors.

- Any statement containing other representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.

When advertising involves the price of drugs or price comparisons, the prices must be exact and the price comparisons must be accurate. When price information is provided, the use of such terms as “*as low as*,” “*and up*,” “*lowest prices*,” or words of a similar nature are discouraged from being used. When price comparisons are made, the person advertising such comparisons must be prepared to provide information sufficient to establish the accuracy of that comparison. Any price advertised for products shall include charges for any related professional services, including dispensing and fitting services, unless the advertisement specifically and clearly states otherwise.<sup>29</sup>

A pharmacist who uses the media to advertise shall not provide any compensation to a media representative for such publicity, unless the fact of compensation is made known in the advertisement used.<sup>30</sup> The law does provide a general guide as to what may be advertised by a pharmacy and a pharmacist. The following types of information may be advertised in the pharmacy profession:<sup>31</sup>

- The name of the practitioner.
- Addresses and telephone numbers of pharmacy operations maintained by the practitioner.
- The hours of operation.
- Languages, other than English, fluently spoken by those providing the pharmacy services.
- A statement that the pharmacy services cover specific types of insurance and third party health plans.
- Names of schools and postgraduate training from which the practitioner has graduated, together with the degrees received.
- A statement of publications authored by the practitioner.

- A statement of the manufacturer, designer, style, make, trade name, brand name, color, size, or type of products advertised.
- Any other item of factual information that is not false or misleading.

***MUST RECORDS OF PRESCRIPTION DRUGS/MEDICAL DEVICES BE RETAINED ON THE PREMISES OF THE LICENSED FACILITY?***

Records of the purchase and dispensing of prescription drugs and medical devices must be maintained at the licensed premises and available for inspection.<sup>32</sup> The original records may only be removed on a temporary basis for a legitimate purpose such as an audit by the State Board of Pharmacy. If any original records are removed, a duplicate set (as copies) must be maintained at the licensed premises.<sup>33</sup> The records described must be retained for three years from the date they were created.<sup>34</sup> If any records are kept electronically, an electronic copy must be made available upon request. The Board may waive the requirement to keep records on the premises if the pharmacy requests the waiver in writing and the request is justifiable.<sup>35</sup> More information on the storage of pharmacy prescription records off-site pursuant to a Board of Pharmacy waiver can be found in *Chapter 9* under the topic heading, *Waiver For Off-Site Storage Of Pharmacy Records*.

***DOES THE FDA REQUIRE A SPECIAL “SIDE-EFFECT” WARNING STATEMENT ON PRESCRIPTION DRUGS?***

Effective January 1, 2009, the FDA requires that pharmacies provide patients with a toll-free number for reporting adverse events experienced while taking their medications. The following statement must appear on the prescription label: *“Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.”*



# REFERENCES TO CHAPTER 8

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2. *Ibid.* at Sec. 1707.2[b-d], 42 U.S.C., Sec. 1396r-8[g], & Brushwood DB, Catizone CA, et.al. *OBRA 90: What It Means to your Practice. U.S. Pharmacist, Oct. 1992, pg. 70*
3. Title 16, Calif. Code of Regs., Sec. 1707.3
4. Calif. State Board of Pharmacy's Consumer Affairs Report, Fall 1990 Newsletter.
5. Calif. Bus. & Prof. Codes, Sec. 4074[d]
6. Title 16, Calif. Code of Regs., Sec. 1707.5[d]
7. Calif. Bus. & Prof. Codes, Sec. 4112 & Title 16, Calif. Code of Regs., 1707.2[b][2][A][B]
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9. Title 16, Calif. Code of Regs., Sec. 1707.2[g]
10. *Ibid.* at Secs. 1707.5[d] and 1707.6
11. Calif. Bus. & Prof. Codes, Sec. 4122[a]
12. *Ibid.* at Secs. 651[a][b][c], 4121, & 17500
13. *Ibid.* at Sec. 4122[c]
14. *Ibid.* at Sec. 4122[e]
15. Title 16, Calif. Code of Regs, Sec. 1744
16. Federal Register, Vol. 63, No. 230, December 1, 1998. Also see, FDA's *Patient Safety Implications On Implementation Of The Current FDA-Mandated Medication Guide Program*, June 2006; and FDA's *Medication Guides – Distribution Requirements and Inclusion In Risk Evaluation And Mitigation Strategies (REMS)*, November 2011.
17. Calif. Bus. & Prof. Code, Sec. 4074[a]
18. Title 16, Calif. Code of Regs., Secs. 1717[a][1][3] & 1744
19. *Ibid.* at Sec. 1744
20. 21 U.S.C. 825[c] and 21 CFR, Sec. 290.5
21. 21 Code of Fed. Regs., Sec. 310.515[a]
22. *Ibid.* at Sec. 310.515[a]
23. *Ibid.* at Sec. 310.501[c][2][4]

24. Bihart, M; *Box Warnings Denotes A Drugs Possible Serious Side Effects or Risks*, Aug. 2008 (<http://drugs.about.com/od/medicationabes/a/BlackBoxWarning.htm>) & Skernivitz, S; *FDA Mandates Drug Label Revisions, Black Box Warnings, Contemporary Pediatrics*, May 7, 2009
25. Title 16, Calif. Code of Regs., Sec. 1717.2[a] is repealed.
26. Calif. Bus. & Prof. Code, Secs. 4341 & 651[a]
27. *Ibid.* at Sec. 17500
28. *Ibid.* at Sec. 651[b]
29. *Ibid.* at Sec. 651[c]
30. *Ibid.* at Sec. 651[d]
31. *Ibid.* at Sec. 651[h]
32. Calif. Bus. & Prof. Code, Sec. 4105[a]
33. *Ibid.* at Sec. 4105[b]
34. *Ibid.* at Sec. 4105[c]
35. *Ibid.* at Sec. 4105[e][1] & Title 16, Calif. Code of Regs., Sec. 1707

## CHAPTER 9

# **THE BUSINESS OF PHARMACY & THE DRUG WHOLESALER**

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### ***ARE THERE RESTRICTIONS ON THE NAME A PHARMACY MAY USE?***

A pharmacy is generally limited in the type of name it may use to advertise itself to the public. If discretion were not somehow implied in the codes, a pharmacy could use such creative names as "The Cocaine House" or "The Drug Shack." Certain names are exclusively restricted to a pharmacy operation and the law prevents businesses or patient care operations that are not licensed by the Board of Pharmacy from using these "restricted" names. Such names as "Pharmacy," "Apothecary Shop," "Drugstore," "Medicine Shop," or any word or words of similar or like import, or the characteristic symbols of pharmacy (such as the "Rx" abbreviation) are strictly reserved for pharmacy operations that are licensed by the Board.<sup>1</sup> If the pharmacy operation is structured as a corporation, the above nomenclature may be used, but the business entity must be identified as a corporation with the use of such descriptions as "Corporation (Corp.);" or "Inc." as part of the title.<sup>2</sup>

### ***WHO MAY OR MAY NOT OWN A PHARMACY IN CALIFORNIA?***

Almost anyone can own a pharmacy in California. That is, you don't have to be a registered pharmacist to file for a pharmacy permit in order to own a pharmacy.<sup>3</sup> All that is required is that a California registered pharmacist be in charge of all prescription medication transactions. California laws do, however, state specific exceptions as to who may not own a pharmacy when certain conditions exist. These exceptions include California licensed prescribers, a person who is married to a California licensed prescriber seeking ownership of a pharmacy where title is vested in both parties' names, and a corporation seeking ownership of a pharmacy where 10% or more of the stock is owned by a California licensed prescriber.<sup>4</sup>



**A. A California Licensed Prescriber**

Section 4111[a][1] of the California Business and Professions Codes states in pertinent part that, "The Board shall not issue any new permit to conduct a pharmacy to... a person or persons authorized to prescribe or write a prescription in the State of California."<sup>5</sup>

If medical devices requiring a prescription are also sold within the pharmacy, then a California licensed chiropractor would also be prohibited from owning that pharmacy since they are authorized to prescribe such devices.<sup>6</sup> The legislative intent in disallowing licensed prescribers from owning pharmacies is simply a conflict of interest concern and an attempt to serve the best interest of the public welfare.<sup>7</sup>

**B. Married Couple where one Spouse is a Prescriber and the other a Pharmacist**

California law also deals with a marital situation where one spouse is a pharmacist and the other is a prescriber. Ownership of a pharmacy by this couple would typically be prevented by law unless title in the pharmacy is held as the "sole and separate property" of the nonprescriber spouse and a separate bank account is maintained. Since California is a "community property" state, any business or property acquired during a marriage belongs to the "community" (the marriage relationship) as a 50%/50% ownership arrangement unless otherwise specified in writing.<sup>8</sup>

If the pharmacy was acquired prior to the marriage, it is deemed the sole and separate property of that party during the marriage unless the title of ownership is changed.<sup>9</sup> In other words, as long as the pharmacy is held in title as the "sole and separate" business of the pharmacist spouse and treated as such, then there should be no problem of ownership if the other spouse is a licensed prescriber. The problem occurs when title is held in the business by

both spouses under a “community property,” “joint tenancy” or “tenants in common” title vesting.<sup>10</sup> Any of these three title vestings would be in conflict with the intent of the pharmacy law.<sup>11</sup>

### *C. A Pharmacy Corporation*

According to Section 4111[a][3] of the California Business and Professions Codes, “A pharmacy corporation that is controlled by, or in which 10% or more of the stock is owned by a California licensed prescriber... will not be issued a permit to conduct a pharmacy.”<sup>12</sup> Thus, a prescriber may own up to 10% of the shares in a pharmacy corporation without being ineligible for permit status. If there is more than one prescriber associated with the corporation, then the total number of shares issued to the collective group of prescribers cannot exceed 10% in order for pharmacy permit status to be granted.

### *D. An Exception to the Exceptions*

The law does not impose as rigid a stance on a pharmacy in a hospital setting as it does for a retail pharmacy operation. Therefore, if the owners of a hospital are a group of physicians exclusively and if the hospital maintains a pharmacy on its premises for inpatient services, then the pharmacy operation is exempt from the exceptions stated in Section 4111[a] discussed above and need not reduce its prescriber ownership rights in the hospital to less than 10%.<sup>13</sup>

This exception appears to extend not only to a hospital pharmacy providing inpatient services, but to one providing outpatient pharmacy services as well. However, for a hospital pharmacy that does provide outpatient services, Section 4111[a] could operate as a challenge for allowing these services to continue if the prescriber ownership of that hospital constitutes more than 10%. It is

of interest to note that the permit that is issued to such an institution is clearly identified as “*restricted to inpatient service only.*” “*Inpatient pharmacy service only*” is interpreted to include all inpatient chart orders, patient discharge medications, and prescriptions for hospital employees.

The Knox-Keene Health Care Service Plan Act of 1975 allows for prescriber ownership in a pharmacy beyond 10% if the entity is a Health Maintenance Organization (HMO).<sup>14</sup>

### ***WHAT BUILDING STANDARDS MUST A PHARMACY MEET?***

The building codes for a community pharmacy have been modified from the older requirements and have been operative since 1996 for the building of new pharmacies or the remodeling of older pharmacies. Such requirements as the 240 square foot minimum store space, the 5 foot barriers, and the 16 square foot minimum counter space for the preparation of pharmaceutical products have been removed from the newer codes. The following represents the revisions, along with the retained standards in the newer regulation:<sup>15</sup>

- All community pharmacies shall contain an area which is suitable for confidential patient counseling. (This wording replaces the earlier requirement stating the need for a self-containing 5 foot barrier enclosing the entire pharmacy. However, keep in mind, you still need a barrier which could reasonably be 5 feet where you do not have a patient counseling area as part of that barrier.)
- The pharmacy's space, fixtures, and equipment shall be properly maintained to ensure that the drugs are safely and properly prepared, maintained, secured and distributed. (This wording replaces the requirement

under the older regulation that a minimum of 16 square feet of counter space must be provided for the preparation of prescriptions for patients.)

- The pharmacy shall be of sufficient and unobstructed area to accommodate the safe practice of pharmacy. (This wording replaces the earlier requirement that a pharmacy must be at least 240 square feet in size.)
- The pharmacy, fixtures and equipment shall be maintained in a clean and orderly condition with proper ventilation and lighting.
- The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.
- Each pharmacist while on duty shall be responsible for the effective control against theft or diversion of prescription drugs and devices.
- Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.
- A pharmacy shall maintain a readily accessible restroom. The restroom shall contain a toilet and washbasin supplied with running water.

The requirements for barriers surrounding the pharmacy are discussed in the next section.

#### ***WHAT SECURITY MATTERS MUST BE CONSIDERED IN OPERATING A PHARMACY?***

In early 1996, Title 16, California Code of Regulations, Section 1712 was repealed. Section 1712 in part stated that "A pharmacy must be separated from the merchandising area by a barrier with a minimum height of five feet and of sufficient width to disallow access by the public to the prescription drugs. An entry door or gate that can be locked must be in place."<sup>16</sup> The repealed Section 1712 was replaced with Section 1714 which does not contain the same above language, but simply notes that there must be in place a reasonable barrier sufficient to prevent access by the public, and that barrier somehow will have incorporated within its structure an area for consultation.<sup>17</sup>

Also, with the repeal of Section 1712 there is no mention in the revised section of having in place a floor to ceiling barrier with a lockable door for operations that open or close the pharmacy section of a business at times other than when the rest of that business is open, as is the case in many chain pharmacy operations. However, this rule is still applicable today since the new regulation (Section 1714) still provides the state Board of Pharmacy with discretion in ensuring that maximum security exists for the pharmacy department.<sup>18</sup>

*A. Who May Enter Into the Pharmacy Area?*

Any person may enter the pharmacy area at the invitation of the pharmacist-on-duty.<sup>19</sup> Certainly, personnel such as the pharmacy intern, pharmacy technician, and pharmacy clerk can work in the pharmacy area, but only when the pharmacist is present on duty in that area, unless there is a policy that allows the pharmacist to be absent from the pharmacy for up to 30 minutes.<sup>20</sup> Usually, if the pharmacist must leave the pharmacy area (e.g. to help a patient choose an over-the-counter drug in the merchandising area), it is not necessary to remove all the pharmacy personnel from the pharmacy area and lock the door or gate. Under normal working conditions if the pharmacist steps away from the pharmacy area, he or she should still be able to be in reasonable view of the pharmacy area.

The pharmacist-on-duty is allowed to have various types of "non-employees" enter the boundaries of the pharmacy, especially those having some business relationship. Drug sales representatives, prescribers, Board inspectors, other law enforcement agents, and janitors are examples of persons who may come back into the pharmacy area, provided they are invited to do so by the pharmacist-on-duty, and as long as the pharmacist is present in that area.<sup>21</sup>



***B. Who May Possess the Key to a Pharmacy?***

The only person ever allowed to possess a key to a pharmacy on their person is a pharmacist.<sup>22</sup> Neither the pharmacy intern nor the pharmacy technician can have possession or dominion and control over the key to a pharmacy. There are a couple of exceptions to this rule, however, for accommodation purposes.

In the case of a hospital pharmacy operation, since hospitals operate 24 hours a day but may not have 24 hour pharmacy services, a designated nurse-in-charge may possess a key to the pharmacy, which must be relinquished to a secured area in the nursing office after the designated nurse-in-charge finishes his or her work shift. Such allowance for access to the pharmacy by non-pharmacist personnel, namely nurses, must be spelled out in written policies and procedures that have been approved by a recognized hospital committee.<sup>23</sup> A designated nurse may enter a hospital's pharmacy for the purpose of obtaining a non-scheduled controlled substance for administration to a patient, but not for dispensing purposes. Any drug removed from the hospital's pharmacy during the absence of a pharmacist should be made record of in writing (entering drug name, strength, and quantity being taken), the designated individual taking the drug, a substantiating medication order by a physician, and the patient who will be receiving the drug.

In a second situation, where the pharmacy area is closed but the rest of a business operation encompassing the pharmacy is still open to the public (as in many chain pharmacy operations), if the key is not kept by the pharmacist-in-charge, it may be placed in an identifiable sealed envelope or container and given to the store's manager to be placed in a secured, locked unit. The store managers are the only persons that have access to this locked unit containing the sealed key. This way, when the pharmacist comes into work the next day, he or she will receive a sealed envelope or container containing the key to the pharmacy.<sup>24</sup>

### ***WHAT PERMIT AND OTHER ARRANGEMENTS MUST BE MADE TO OPERATE A PHARMACY?***

A permit or license to operate a pharmacy must be granted by the Board of Pharmacy. If medical devices are sold within the pharmacy, only the pharmacy permit is required.<sup>25</sup> However, if a pharmacist owns two or more pharmacies, each located at different addresses, then two or more permits or licenses must be applied for and issued for each different address.<sup>26</sup> One site license is issued if a pharmacy is to be maintained on the single premise, a second license for that site would be required if the pharmacy intends to compound sterile injectable drugs. The Board has defined the licensed premise as being a "location with its own address and an independent means of ingress and egress."<sup>27</sup>

A pharmacy owner who is not a pharmacist and family member of a pharmacist owner (but no one more than the aforementioned) may possess a key to the pharmacy that is to be maintained in a tamper-free container (such as a sealed envelope) for the purpose of 1) delivering the key to a pharmacist, or 2) providing access in case of an emergency (e.g. fire, flood, or earthquake). The signature of the pharmacist-in-charge shall be placed on the container in such a way that the pharmacist may easily determine whether or not the key has been removed from the container.<sup>28</sup>

The permit or license that is issued by the Board must be renewed annually and shall not be transferable.<sup>29</sup> To "not be transferable" means that the permit may not be passed to a new owner who buys a pharmacy. The new owner must apply for a separate permit or license.<sup>30</sup> During the course of a pharmacy transfer, the Board has the discretion to issue a temporary permit for a period of up to 180 days.<sup>31</sup> During the time that the temporary permit is issued, the Board will determine that the continued operation of the pharmacy does not in any way jeopardize the safety of the public, before issuing the permanent pharmacy permit or license.<sup>32</sup>

When the pharmacy permit is issued, it must be posted in a conspicuous place within the pharmacy area.<sup>33</sup> Further, it was noted in the October 1998 edition of the Board of Pharmacy's publication, *The Script*, that "pharmacists and other board-licensed personnel are no longer required to display their individually issued state Board of Pharmacy licenses."<sup>34</sup>

**A. What Information Must be Contained in an Application for Pharmacy Licensure?**

The general information required on the application that must be filed in order to obtain a pharmacy permit (the same information is required for a veterinary food-animal drug retailer permit) is as follows:<sup>35</sup>

- The name and address of the applicant owner or owners.
- The name and address of the pharmacy.
- The name of the pharmacist-in-charge. In the case of a veterinary food-animal drug retailer, the name of the representative-in-charge must be noted.<sup>36</sup>
- The occupation and professional qualifications of the applicant. If the applicant is not a natural person (meaning that applicant is a partnership or corporation) then the following must be provided:
  - The beneficially interested parties to the pharmacy or veterinary food-animal drug retailer business venture.
  - The names of directors, officers, and shareholders if the pharmacy venture or veterinary food-animal drug retailer business is to be set up as a corporation.
  - If the number of partners, members, or stockholders exceeds five, the application shall so state. The names, positions, professional qualifications, and occupations of the top five interest holders must be provided.
  - A statement declaring that the applicant has never been convicted of a felony.

- A statement declaring that the applicant has never violated any law pertaining to the practice of pharmacy.
- If there is any change in the beneficial ownership interest, which includes changes in corporate officers, as well as the owners and pharmacist-in-charge, such changes shall be reported to the Board of Pharmacy within 30 days thereafter upon a form to be furnished by the Board.<sup>37</sup> The following additional changes in ownership requiring notice to the Board are:
  - Any transfer of 10% or more of the beneficial interest in the business entity licensed by the Board to another person or entity who did not hold a beneficial interest at the time the original permit was issued, shall require written notice to the Board within 30 days of such transfer changes.<sup>38</sup>
  - When there is a transfer of 50% or more of a beneficial interest to any person or entity who may or may not already have some beneficial interest in the subject business licensed by the Board, then a new application for change of ownership must be filed for the issuance of a new permit.<sup>39</sup>

The permit issued shall be renewed annually and shall not be transferable.

**B. What Happens to a Pharmacy Permit if the Pharmacy Closes or is Closed by the Board of Pharmacy?**

The Board of Pharmacy can void a pharmacy permit if the pharmacy remains closed for an indefinite time, or is closed by the Board. The pertinent statute defines "closed" as "not engaged in the ordinary activity for which a license has been issued for at least one day each week during any 120-day period."<sup>40</sup> In a case where a pharmacy is closed

at the owner's discretion and no notification is made to the Board of such closure, the Board shall make a diligent, good faith effort to give notice by personal service on the licensee.

If no written objection is received by the Board within 10 days after personal service, the Board may void the license without the necessity of a hearing. If a written objection is filed by the licensee in a timely manner, a Board hearing shall be scheduled.<sup>41</sup>

In the event that a pharmacy permit is revoked by the Board, or the permit holder advises the Board that he or she plans to discontinue doing business, the permit holder shall, within 10 days of the notification, arrange for the transfer of all dangerous drugs and controlled substances or medical devices to another licensed pharmacy or medical device retailer. When the transfer has taken place, the permit holder who makes the transfer shall immediately confirm in writing to the Board that the transfer has occurred.<sup>42</sup> If the permit holder does not comply with the completion of the transfer and notification of the Board, then the Board may, by order of a superior court within the jurisdiction where the pharmacy is located, obtain authorization to enter the pharmacy, inventory the prescription drugs and/or devices, and transfer, store, and sell the drugs and/or devices.<sup>43</sup>

The Board may retain from the proceeds of any sale it conducts an amount equal to the costs of obtaining and enforcing the court order. The remaining proceeds shall be returned to the permit holder.<sup>44</sup> If the Board notifies the permit holder of the proceeds available to him or her after the sale, and the permit holder does not respond within 30 calendar days of the notice, then the Board has the right to deposit the permit holder's share of the proceeds into the Pharmacy Board's "Contingency Fund."<sup>45</sup>



**C. Are Other Permits Besides the Pharmacy Permit  
Required to Operate a Pharmacy?**

At one time, separate permits were required in order for prophylactics, hypodermic needles, and syringes to be stocked and sold by pharmacies. This is no longer the case since the pharmacy permit is all-inclusive for the stocking and selling of such items. However, a separate permit is required from the Federal Drug Enforcement Administration (DEA) in order for a pharmacy to buy and dispense controlled substances. The pharmacy must apply for this special permit separately from the pharmacy permit. If a pharmacy opts not to fill prescriptions for controlled substances, it is not mandatory for the pharmacy to have a permit for the sale of controlled substances.<sup>46</sup>

Community pharmacies who are presently compounding or wish to compound sterile injectable products must acquire an annual license from the Board of Pharmacy for this purpose.<sup>47</sup> The regulations detailing the operational requirements of a pharmacy engaged in the compounding of sterile injectable products are discussed in Chapter 11 (*Compounding And Manufacturing Issues In Pharmacy Practice*). The applicable laws pertaining to sterile injectable compounding can also be found within Title 16, California Code of Regulations, Sections 1751 through 1751.12.

The Board presently has the authority, upon reasonable belief, to issue a cease and desist order to a pharmacy regarding its sterile injectable product compounding if there is an immediate threat to the public.<sup>48</sup> Pharmacy operations licensed by the California Department of Health Services (DHS) and are subjected to the Joint Commission Accreditation of Healthcare Organizations (JCAHO) are exempt from the Board's special licensing requirements.<sup>49</sup> A community pharmacy that is involved in the reconstitution of a sterile powder shall not require a license if 1) the sterile powder for reconstitution was obtained from a manufacturer, and 2) the drug is reconstituted for administration to patients by a health

care professional licensed to administer drugs by injection.<sup>50</sup> Both of the above two conditions must be met to defer the community pharmacy operation from separate licensing.<sup>51</sup>

**D. Does a Clinic Require a Permit to Stock and Dispense Drugs?**

As a general rule, a clinic may purchase drugs at wholesale prices to be administered or dispensed by licensed prescribers to patients registered for care at the clinic if the clinic is licensed by the Board of Pharmacy.<sup>52</sup> In order to obtain permit privileges from the Board, the clinic must fully comply with all laws that ensure that inventories, security procedures, personnel training, protocol development, record-keeping, packaging, labeling, dispensing procedures, and patient consultation occur in a manner that is consistent with the promotion and protection of public health and safety.<sup>53</sup> Written policies and procedures shall exist at each clinic facility clearly defining the pharmacy services based upon the statutes and regulations applicable to the operation of a clinic pharmacy. The policies and procedures shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.<sup>54</sup>

Drugs may be dispensed from the clinic by the physician, a pharmacist, or other person lawfully authorized to dispense drugs (as outlined in the clinic's policy and procedures).<sup>55</sup> The clinic must keep records regarding all drug purchases, administrations, and dispensing for a minimum of a three year period.<sup>56</sup> No Schedule II controlled substance shall be dispensed by the clinic.<sup>57</sup> This does not, however, bar or prohibit a physician from dispensing a Schedule II drug to the extent permitted by law. The clinic prescriber may either write a Schedule II controlled substance prescription to give to the patient or dispense/administer the Schedule II drugs from his or her own personal ordered supplies.

There must be evidence in the clinic's application for a pharmacy license that a consulting pharmacist is retained,

and that the consulting pharmacist will visit the clinics regularly and at least quarterly each year to ensure that all pharmacy policy and procedures are being followed, and to institute changes, additions or deletions in policy where appropriate.<sup>58</sup> It will be the responsibility of the consulting pharmacist to certify in writing to the Board quarterly each year that the clinic is, or is not, in compliance with carrying out its policies and procedures, or in compliance with all applicable pharmacy laws. Each completed quarterly certification report shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.<sup>59</sup>

While the statutory law outlines the required procedures regarding the ordering, storing and dispensing of prescription drugs within the clinic setting, there are some differences in the pharmacy-related requirements when the clinic is designated as a “general” clinic as compared to a “surgical” clinic. The “general” clinic category includes: 1) non-profit community clinics, 2) free clinics, and 3) non-profit multispecialty clinics. “Surgical” clinics are those clinics engaged only in surgical procedures.

For the most part, the laws that apply to a “general” clinic also apply to a “surgical” clinic. There are, however, some subtle differences regarding the involvement of a pharmacist and the use of drugs within the surgical clinic. Among those differences are the following:

- The surgical clinic is to be limited to the use of drugs for administration to the patients seeking the surgical procedures performed at the clinic and to the dispensing of drugs for the control of pain and nausea.<sup>60</sup>
- If a patient requires a take-home medication from the surgical clinic, no more than a 72 hour amount can be provided to the patient to meet their immediate medical needs.<sup>61</sup>
- While no Schedule II controlled substances can be dispensed at the surgical clinic, such drugs may be administered on the premises of the clinic.<sup>62</sup>

- A consulting pharmacist is also required for a surgical clinic if drug supplies exist. As with the general clinic, the surgical clinic's consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements set forth in the law or conform to proper standards of pharmacy practice for the well being of the patients served. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.<sup>63</sup>

***E. Does a Hospital Require a Permit to Order, Store, and Dispense Drugs?***

Regardless of size, any hospital involved in the ordering, storing, and dispensing of drugs must have a permit issued by the State Board. A permit shall be issued on an annual basis upon filing of an application with the Board. The application must contain, among other items:<sup>64</sup>

- The name and address of the applicant,
- The number of beds,
- Whether the applicant is a licensed or county hospital,
- Whether it does or does not employ a full-time registered pharmacist,
- The name of the pharmacist-in-charge,
- The form of ownership, and
- The name of the chief medical officer and administrator.

Although all hospitals, regardless of size, must have a permit from the board of pharmacy for the ordering, stocking and dispensing of drugs, hospitals with 100 beds or less may not have to employ a full-time pharmacist, but must employ a consultant pharmacist who shall be responsible for preparing written reports and recommendations regarding the pharmaceutical services in the hospital.<sup>65</sup> These reports are to be made available to the Board quarterly.<sup>66</sup> The hospital must also keep records of the kind



and amounts of drugs purchased and administered. These records also must be available for inspection by authorized personnel of the Board of Pharmacy.<sup>67</sup>

The license for operating a hospital pharmacy shall be renewed annually on or before November 1 of each year.<sup>68</sup>

**F. Do Out-Of-State Manufacturers, Wholesalers, or Pharmacies Doing Business in California Require a Permit to Operate in this State?**

Any out-of-state manufacturer, wholesaler, or pharmacy which sells or distributes drugs (including dangerous medical devices) in this state, must obtain an "out-of-state drug distribution license" or a "non-resident pharmacy registration" from the California State Board of Pharmacy.<sup>69</sup> Such licenses or registration permits shall be renewed on an annual basis and shall not be transferable.<sup>70</sup>

Generally, the type of pharmacy operation that requires a "non-resident pharmacy registration" is a mail order pharmacy doing a substantial amount of pharmacy-related business in the State of California.

**G. Must a Pharmacy Located Outside the Physical Plant of a Hospital, Serving that Hospital, be Separately Licensed?**

A pharmacy serving a hospital may be located outside of the hospital in another physical plant as long as it is regulated under the hospital's consolidated license issued by the Board of Pharmacy, and therefore does not require a second license. As a condition of single licensure, the pharmacy shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located.<sup>71</sup>



### ***HOW MAY A CONTRACT FOR PHARMACY SERVICES IN A HOSPITAL BE STRUCTURED?***

If a pharmacist or pharmacy corporation intends to enter into a contract with a hospital to provide pharmaceutical supplies and services, the basis of the contractual agreement cannot be predicated on a percentage reimbursement by the hospital to the pharmacy contractor. Thus, any percentage contract agreement related to patient charges or based on hospital and/or pharmacy revenues or costs for pharmaceutical products or services provided, is strictly forbidden.<sup>72</sup> A "Pharmacy-Hospital Contract" can, however, base its reimbursement schedule on a direct billing for the costs of all pharmaceutical products or services rendered to each patient by the contracting pharmacy.

### ***WAIVER FOR OFF-SITE STORAGE OF PHARMACY RECORDS***

A pharmacy, upon request, may be granted a waiver by the Board of Pharmacy for off-site storage of its records.<sup>73</sup> (An off-site storage area is a facility that has a different address than the licensed facility; thus, placing records in a back room at the same address of the licensed facility does not require a waiver from the Board.)<sup>74</sup> The major requirements in storing pharmacy records in an off-site storage facility require:

- That the facility be secure from unauthorized access;
- That confidentiality of the contained records be maintained; and
- That the pharmacy be able to produce the requested records from the off-site facility within 48 hours or within two business days.<sup>75</sup>

Failure for the pharmacy to comply with any of the three items stated above allows the Board of Pharmacy to cancel the waiver immediately and without a hearing.<sup>76</sup> If a pharmacy's waiver for off-site storage is canceled, the

pharmacy may reapply for the waiver upon demonstrating to the Board that the pharmacy is presently in compliance with the requirements of the regulation.<sup>77</sup>

As to the question as to when prescription records can be moved from the license premises to a premises granted in the form of a waiver by the Board of Pharmacy, the law allows the following:

- Prescription records for non-controlled substances can be moved to the off-site storage area after one year from the last date of dispensing this category of medications.<sup>78</sup>
- Prescription records for controlled substances can be moved to the off-site storage area after two years from the last date of dispensing this category of medications.<sup>79</sup>

### *LAW PERTAINING TO CLOSED DOOR PHARMACIES*

California Senate Bill 1307 was passed in September 2004 and notes the following regarding “closed door” pharmacy operations; that the law would require a wholesaler to keep track and report to the Board of Pharmacy excessive purchases of dangerous drugs by a closed door pharmacy (a pharmacy not routinely engaged in the ordinary practice of pharmacy). Excessive purchases by a closed door pharmacy could be construed as unprofessional conduct, and cause that business operation to be investigated by the Board of Pharmacy.<sup>80</sup> Some closed-door pharmacies have come under scrutiny primarily because of being involved in the sale of a narrow selection of drugs like *Viagra*® and *Vicodan*, usually in higher volumes than normal and in a manner that might suggest that adequate or good faith examinations by prescribers may not be properly conducted.

### ***TEMPORARY USE OF A MOBILE PHARMACY***

If a pharmacy should be destroyed or made non-accessible, the Board may allow for the temporary use of a mobile pharmacy if the following conditions are met:<sup>81</sup>

- The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.
- The mobile pharmacy will continue to be under the control and management of a pharmacist-in-charge.
- A licensed pharmacist is on the premises of the mobile unit while drugs are being dispensed.
- Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.
- The pharmacy operating the mobile pharmacy provides the Board with records of the destruction of, or damage to, the pharmacy and an expected restoration date.
- Within three calendar days of restoration of the pharmacy services, the Board is provided with notice of the restoration of the permanent pharmacy.
- The mobile pharmacy is not operated for more than 48 hours following the restoration of the permanent pharmacy.

### ***THE MEDICATION PEDIGREE REQUIREMENTS FOR WHOLESALERS AND PHARMACIES***

Starting January 1, 2016, a wholesaler or repackager of drugs may not sell, trade, or transfer a prescription drug at wholesale without providing a pedigree..<sup>82</sup> The concept of establishing a “pedigree” for each dangerous drug would ensure that it is obtained from a reliable and FDA licensed manufacturer and is carefully monitored as it proceeds through the distribution chain, and is guaranteed to be exactly the drug and strength indicated on the packaging that will be dispensed to the ultimate consumer or patient.

A pharmacy would also be prohibited, as of July 1, 2017, from selling, trading, or transferring a dangerous drug or medical device without a pedigree or a receipt for such drugs or devices establishing the drug's or medical device's pedigree.<sup>83</sup>

### ***RESPONSIBILITY OF A DRUG MANUFACTURER OR WHOLESALER***

All drug manufacturers and wholesalers who distribute drugs in California must be licensed by the California State Board of Pharmacy.<sup>84</sup> Licensed drug wholesalers and distributors are required to ensure proper storage, security, ordering, distributing procedures are in place for all drug products at their site, and are required to maintain operational policies and procedures ensuring that every aspect of their operations are in compliance with both federal and state laws. It is the responsibility of licensed drug manufacturers and wholesalers to report any unusual or larger than normal sales to pharmacies of dangerous drugs. A system shall be in place capable of detecting variances in ordering patterns by the same customer over a 12 month period. Those customers that will be identified are where their purchases exceed 20% as compared to the last 12 month period.<sup>85</sup> If excess amounts of drug purchases are made in the amount noted over the course of the last 12 month period, a report of such purchasing by a pharmacy must be made to the Board within 30 days upon this finding.<sup>86</sup>

### ***WHAT ARE SOME ADDITIONAL DRUG WHOLESALER AND DISTRIBUTOR REQUIREMENTS?***

#### ***A. Wholesale License Requirements Within The State***<sup>87</sup>

- A wholesaler of any dangerous drug or device, as noted previously, must be licensed by the Board.
- A separate license shall be required for each place of business owned or operated by a wholesaler.

- Each wholesaler must designate a representative-in-charge who shall be licensed as such by the Board. The representative-in-charge shall be responsible for ensuring that the wholesale operation is in total compliance with state and federal laws. If a representative-in-charge leaves the employment of a wholesaler, the wholesaler must identify a new representative-in-charge within 30 days after the prior representative-in-charge leaves. The representative-in-charge does not have to be a pharmacist.
- A drug manufacturer licensed by the FDA that only ships dangerous drugs or devices of its own manufacture is exempt from this section.
- The Board may issue a temporary license for up to 180 days in order to protect public safety if there is a change in wholesaler ownership.

***B. Out-Of-State Wholesalers Or Distributors Of Drugs***

- An entity located outside the state that ships, mails, or delivers dangerous drugs or devices must be licensed by the Board prior to shipping, mailing or delivering such drugs or devices within the State.<sup>88</sup>
- A temporary license may be issued by the California State Board of Pharmacy to either a drug wholesaler or an out-of-state distributor for a period not to exceed 180 days in order to protect public safety.<sup>89</sup>
- An out-of-state wholesaler of drugs or devices that is licensed in California shall be referred to as a "nonresident wholesaler."<sup>90</sup>
- The license must be renewed annually and is nontransferable. Manufacturers of drugs or devices who ship their own product directly into California are exempt from the license requirement.<sup>91</sup>
- A registered pharmacist of the state the wholesale operation resides in, or a representative-in-charge must be present and in control of the wholesaler's premises during the conduct of business.<sup>92</sup>



Bottom line, a non-resident drug wholesaler or distributor must be registered with the California Board of Pharmacy before providing prescription drugs or medical devices to California entities.

***C. Wholesaler License Surety Bond Requirement***<sup>93</sup>

- An applicant for the issuance or renewal of a wholesaler license shall submit a surety bond of \$100,000 or other equivalent means of security acceptable to the Board. A lesser amount may be secured if the annual gross receipts of the previous tax year for the wholesaler is \$10,000,000 or less, in which case the surety bond shall be \$25,000.
- The purpose of the surety bond is to secure payment of any administrative fine imposed by the Board and any other legal costs incurred.
- The Board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

***D. Pedigree Tracking of Prescription Drugs***

Federal and state laws are beginning to be put in place to address the drug “pedigree” issue. The creation of such laws are important to ensure that every drug product that enters the marketplace and moves through the stream of commerce is what it purports to be as noted on the product label. By definition, “pedigree” means “a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.”<sup>94</sup> An “interoperable electronic system” means an electronic track and trace system for drugs that uses a unique identification number, established at the point of manufacture.

Implementation, as dictated by the California Legislature, of a pedigree tracking system for all prescription

drugs in California, should be achieved prior to January 1, 2016 for drug wholesalers and repackagers, with full implementation by January 1, 2017 for pharmacies and pharmacy warehouses.<sup>95</sup>

A pedigree shall include the following information:<sup>96</sup>

- The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number, and principal address of the source.
- The trade or generic name of the drug, the quantity, dosage form, strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.
- The business name and address, and the drug's shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.
- A certification from a responsible party of the source of the drug that the information contained in the pedigree is true and accurate.
- A single pedigree shall include every change of ownership of a given drug from its initial manufacture through to its final transaction to a pharmacy... regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.

The following transactions are not required to be recorded on a pedigree:<sup>97</sup>

- Samples of prescription drugs provided to a prescriber by the manufacturer by a manufacturer's employee.
- An injectable dangerous drug that is provided directly to a prescriber or other health care provider that is responsible for administration of the injectable drug to a patient.
- An "intracompany" sale or transfer.
- Drugs delivered by the federal government to a local or state government entity.
- The sale, trade, or transfer of a radioactive drug between any two entities licensed by the Radiologic Health Branch of the State Department of Public Health, and the federal Nuclear Regulatory Commission.

- The sale, trade, or transfer of veterinary drugs.
- The sale, trade, or transfer of intravenous solutions intended for the replenishment of fluids and electrolytes, for dialysis, or for irrigation or reconstitution, as well as sterile water.
- Drugs contained in packages combined with medical supplies or equipment to be used for surgical procedures.

***WHO MAY SIGN FOR ORDERED DRUGS  
FROM A WHOLESALER WHEN THEY  
ARRIVE AT THE PHARMACY?***

Only a pharmacist or pharmacist intern may sign for the receipt of prescription medications that are delivered by the wholesaler to the pharmacy.<sup>98</sup> The statute that requires this also further states, "...a designated representative may also sign for and receive the delivery."<sup>99</sup> It is important to note that this language does not give authority for signing off on received drugs from the wholesaler or distributor by either pharmacy clerks or technicians, since Calif. Business & Professions Code, Section 4022.5[a] gives specific meaning to what is meant by a "designated representative." Designated representative according to the code is an individual to whom a license has been granted to operate a veterinary food-animal drug business and is either a representative-in-charge, or a representative of such an operation.<sup>100</sup>

***OTHER SITUATIONS WHEN A DELIVERY  
IS MADE BY THE DRUG WHOLESALER?***

Other situations where dangerous drugs or devices are delivered by a drug wholesaler or drug distributor:<sup>101</sup>

- Deliveries of dangerous drugs or devices to a hospital pharmacy may be made to a central receiving location within the hospital. The dangerous drugs or devices shall then be delivered to the licensed pharmacy premises within one working day following receipt by the hospital,

and the pharmacist on duty at the time of such delivery shall immediately inventory the dangerous drugs or devices.

- A dangerous drug or device ordered and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor (Calif. Bus. & Prof. Code, Sec. 3640.7), laboratory, or a physical therapist; must have the person or entity receiving that drug or device, or a duly authorized representative of the person or entity, sign for the receipt of the delivered drugs or devices.
- A dangerous drug or device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or devices are to be transferred, sold, or delivered. It must be determined that the recipient of any dangerous drug or device in this state, another state, or country is authorized by law to receive the dangerous drugs or devices.
- A pharmacy may take delivery of dangerous drugs and devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:
  - The drugs are placed and locked in a secure storage facility in the same building as the pharmacy.
  - Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or devices have been delivered.
  - The secure storage facility has a means of indicating whether it has been entered into after the dangerous drugs or devices have been delivered.
  - The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and devices to a secure storage facility.
  - The agent delivering dangerous drugs and devices leaves documents indicating the name and amount of

each dangerous drug or device delivered in the secure storage facility.

### ***CALIFORNIA LABOR LAW CODES AFFECTING PHARMACIST'S EMPLOYMENT EXEMPTION STATUS***

According to changes in the California Labor Law Codes (as of 1/1/2000) pharmacists are no longer characterized as "exempt" employees. Section 851 through 856 of the Labor Codes sets the limits as to how many hours per two week period a pharmacist or any nonexempt employee may work. These specific sections of the Code prevents any pharmacist working in a prescription area that services patients to perform more than 108 hours of work (or twelve days) in any two week period.<sup>102</sup> This work arrangement is broken down to a 9-hour day (includes one hour of time for meal periods and other breaks). This suggests a period of 54 hours of work per week at 9 hours a day for six days, with one day of rest during the seven-day week.<sup>103</sup> As stated, this particular section of the Labor Codes sets the limit as to how many hours a week any nonexempt employee can work before an employer is to be considered in violation of the code.

Sections 510 through 558 of the California Labor Code describes when the pharmacist is entitled to overtime pay, the amount of that overtime pay, and the general exceptions to the "non-exemption" rule for employee pharmacists. According to the Code, any work performed beyond 8 hours per day or 40 hours a week entitles the employee to overtime at the following rates:<sup>104</sup>

- 1½ times pay beyond 8 hours per day or 40 hours per week.
- 2 times pay beyond 12 hours per day.

Exceptions to the above overtime allowances and the "non-exemption" status are so far characterized by the following circumstances:<sup>105</sup>



- An employee working in an executive or administrative capacity. The definition of administrative or executive pharmacy positions has not been totally settled. Generally, a pharmacist employee designated as a *pharmacist-in-charge* or *pharmacy store manager* appears to be recognized as a nonexempt employee who performs his or her duties within a prescription-filling area. It appears that as long as the pharmacist, regardless of his or her title, is working within the patient care area and is involved with the processing of drugs for patients or is directly supervising pharmacists performing pharmaceutical care services for patients, then that pharmacist is still considered a nonexempt employee.
- Where the employees of an operation adopt by a 2/3rds vote an alternative workweek at no longer than 10 hours per day and 40 hours per week.
- Where an alternative workweek is adopted pursuant to a collective bargaining agreement.
- In cases of emergency or where there is a need to protect life.
- Where a pharmacist employee works at one pharmacy operation 40 hours a week while working part-time at another pharmacy. (Each pharmacy is a separate entity and not responsible for additional work the pharmacist employee pursues at a second or third pharmacy.)

# REFERENCES TO CHAPTER 9

1. Calif. Bus. & Prof. Codes, Sec. 4343
2. *Ibid.* at Sec. 4152
3. *Ibid.* at Sec. 4110[a]
4. *Ibid.* at Sec. 4111[a][1][3]
5. *Ibid.* at Sec. 4111[a][1]
6. *Ibid.* at Sec. 4111[a][1]
7. *Magan Medical Clinic v. California State Board of Medical Examiners* 249 CA2d 124, 57 Cal Rptr 256, (1967, 2<sup>nd</sup> Dist.)
8. Calif. Civ. Code. Sec. 682.1[a] & Calif. Family Code, Sec. 760
9. Calif. Family Code, Sec. 761[a][b][c]
10. A “community property” title vesting denotes that the husband and wife each own 50% of the property or business. If the husband and wife own the business as “joint tenants,” technically each owns 100% of the business. When the business is held in a “tenants in common” arrangement, then any percentage of ownership can be agreed upon (if no specific percentages are stated, it will automatically be a 50% interest held by each spouse).
11. Calif. Bus. & Prof. Codes, Sec. 4111[a][2]
12. *Ibid.* at Sec. 4111[a][3]
13. *Ibid.* at Sec. 4111[b]
14. Calif. Health & Safety Codes, Sec. 1340, Calif. Bus. & Prof. Code, Sec. 4111[d]
15. Title 16, Calif. Code of Regs, Sec. 1714
16. Title 16, Calif. Code of Regs., Sec. 1712 (Repealed 3/1/96) leaving Sec. 1714 in effect.
17. Calif. Bus. & Prof. Codes, Sec. 4118[a] & Title 16, Calif. Code of Regs., Sec. 1714[a][b][d]
18. Title 16, Calif. Code of Regs., Sec. 1714[d]
19. Calif. Bus. & Prof. Codes, Secs. 4116[a] & 4117
20. Title 16, Calif. Code of Regs.. Sec. 1714.1[e]
21. Calif. Bus. & Prof. Codes, Secs. 4116[a] & 4117
22. Title 16, Calif. Code of Regs., Sec. 1714[d]
23. Title 22, Calif. Code of Regs., Secs. 70261[q][8], 70263[c][1] & 70263[n]
24. Title 16. Calif. Code of Regs., Sec 1714[e]
25. Calif. Bus. & Prof. Code, Sec. 4110[a]
26. *Ibid.* at Sec. 4110[a]
27. *Ibid.* at Sec. 4107
28. Title 16, Calif. Code of Regs., Sec. 1714[e]

29. Calif. Bus. & Prof. Codes, Sec. 4110[a]
30. *Ibid.* at Sec. 4110[a]
31. *Ibid.* at Sec. 4110[b]
32. *Ibid.* at Sec. 4110[b]
33. *Ibid.* at Sec. 4058
34. *Ibid.* at Sec. 4058 & *The Script*, Oct. 1998 Edition.
35. *Ibid.* at Sec. 4201[a-i] & Title 16, Calif. Code of  
Regs., Sec. 1709[a]
36. Calif. Bus. & Prof. Codes, Secs. 4196[a][d]
37. Title 16, Calif. Code of Regs., Sec. 1709[a]
38. *Ibid.* at Sec. 1709[b]
39. *Ibid.* at Sec. 1709[c]
40. Calif. Bus. & Prof. Codes, Sec. 4312[a][e]
41. *Ibid.* at Sec. 4312[a]
42. *Ibid.* at Sec. 4312[b]
43. *Ibid.* at Sec. 4312[c]
44. *Ibid.* at Sec. 4312[d]
45. *Ibid.* at Sec. 4312[d][3]
46. Title 22, Code of Fed. Regs. (CFR), Sec. 1301.11[a]
47. Calif. Bus. & Prof. Codes, Sec. 4127.1[a]
48. *Ibid.* at Sec. 4127.3
49. *Ibid.* at Sec. 4127.1[d]
50. *Ibid.* at Sec. 4127.1[e]
51. *Ibid.* at Sec. 4127.1[e]
52. *Ibid.* at Sec. 4180[a][b]
53. *Ibid.* at Sec. 4181[a]
54. *Ibid.* at Sec. 4181[a]
55. *Ibid.* at Sec. 4181[c]
56. *Ibid.* at Sec. 4180[a][F][2]
57. *Ibid.* at Sec. 4184
58. *Ibid.* at Sec. 4182[a]
59. *Ibid.* at Sec. 4182[b]
60. *Ibid.* at Sec. 4190[b]
61. *Ibid.* at Sec. 4190[b]
62. *Ibid.* at Sec. 4194
63. *Ibid.* at Sec. 4192[b]
64. Calif. Bus. & Prof. Codes, Sec. 4056[d] – Also see 4028, 4029,  
4052.1 & Title 16, Calif. Code of Regs., Sec. 1709
65. Title 22, Calif. Code of Regs., Secs. 70263 & 70265
66. *Ibid.* at Secs. 70263 & 70265
67. Calif. Bus. & Prof. Codes, Sec. 4056[a]

68. *Ibid.* at Sec. 4056[c]
69. *Ibid.* at Secs. 4120[a][b] & 4161[a][b]
70. *Ibid.* at Sec. 4160[c] & 4161[c]
71. *Ibid.* at Sec. 4029[b]
72. *Ibid.* at Sec. 650.1[a]
73. Title 16, Calif. Code of Regs., Sec. 1707[a]
74. *Ibid.* at Sec. 1707[g]
75. *Ibid.* at Sec. 1707[b]
76. *Ibid.* at Sec. 1707[c]
77. *Ibid.* at Sec. 1707[d]
78. *Ibid.* at Sec. 1707[e]
79. *Ibid.* at Sec. 1707[f]
80. Calif. Bus. & Prof. Code, Sec. 4164 & Title 16, Calif. Code of Regs., Sec. 1782
81. Calif. Bus. & Prof. Code, Sec. 4110[c]
82. Calif. Bus. & Prof. Codes, Sec. 4163[c]
83. *Ibid.* at Secs. 4163[e]
84. *Ibid.* at Sec. 4160[a][b]
85. Title 16, Calif. Code of Regs., Sec. 1782, & Calif. Bus. & Prof. Codes, Sec. 4164[b]
86. Title 16, Calif. Code of Regs., Sec. 1782
87. Calif. Bus. & Prof. Codes, Sec. 4160
88. *Ibid.* at Sec. 4161[a]
89. *Ibid.* at Sec. 4160[g]
90. *Ibid.* at Sec. 4161[a]
91. *Ibid.* at Sec. 4160[c][f]
92. *Ibid.* at Secs. 4053 & 4160[d]
93. *Ibid.* at Sec. 4162.5
94. *Ibid.* at Sec. 4034[a]
95. *Ibid.* at Secs. 4163 & 4163.5
96. *Ibid.* at Sec. 4034[b] & *The Script*, Feb. 2009, pg. 5
97. *Ibid.* at Sec. 4034[g]
98. *Ibid.* at Sec. 4059.5[a]
99. *Ibid.* at Sec. 4059.5[a]
100. *Ibid.* at Sec. 4022.5[a]
101. *Ibid.* at Sec. 4059.5
102. Calif. Labor Code, Sec. 851
103. *Ibid.* at Sec. 852
104. *Ibid.* at Secs. 510 through 558
105. *Ibid.* at Secs. 510 through 558

# CHAPTER 10

## SPECIAL DRUG PRODUCTS AND DEVICES

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***CAN A PHARMACIST GENERICALLY SUBSTITUTE  
A DRUG OR CHANGE THE DOSAGE FORM WHEN A  
PRESCRIBER WRITES FOR A "TRADE NAME"  
PRODUCT OR A SPECIFIC DOSAGE FORM?***

When a prescription is written using either the trade (brand) name or generic name of a drug, the pharmacist is at liberty to dispense a drug with the same active chemical ingredients, strength, quantity and dosage form as the prescribed product.<sup>1</sup> Extremely important in generic drug substitution is that the substituted drug must have the same active chemical ingredients. This means that the substituted drug must be the same identical salt as the prescribed brand name drug.<sup>2</sup>

The purpose of the drug substitution law is to provide a cost saving advantage to the consumer. Therefore, when a generic drug substitution is made, it must be communicated to the patient that the substitution will provide a cost savings to him or her.<sup>3</sup> Also, either the trade name or the manufacturer's name (if the generic name is used) must be typed on the label affixed to the dispensed drug container.<sup>4</sup>

In addition to the pharmacist generically substituting a drug that has the same chemical constituency, he or she may now also substitute a drug with a different form of the medication having the equivalent strength and duration of effect (e.g. capsule to a tablet, or tablet to an oral liquid), unless the prescriber indicates no substitution be made, and the change is in the patient's best interest.<sup>5</sup> The purpose for the change in dosage form without the prescriber's authorization is to improve the patient's ability to comply with the prescribed drug therapy. Therefore, as an example, if you run out of a specific cream and wish to provide the same drug in the form of an ointment, two factors could serve as a challenge to this type of dosage form substitution:

- Fundamentally an ointment base is different from a cream base, and technically might change the rate of drug delivery. If this happened to be a drug

prescribed by a dermatologist, he or she had a purpose in mind in giving one of the dosage forms over the other.

- Because you may run out of one type of dosage form and substitute it with another may not be within the intent of the statute – “...*the change will improve the ability of the patient to comply with the prescribed drug therapy.*”<sup>6</sup> Essentially, the change may have been made to benefit the pharmacy and not necessarily the patient.

A prescriber can, by expressed means, prohibit a pharmacist from providing the patient with a generically equivalent drug when he or she has written for a trade or brand name item by doing any of the following:<sup>7</sup>

- Orally stating to the pharmacist that he or she does not want any drug substitution.
- Stating in his or her own handwriting that he or she does not want any drug substitution.
- Checking the box on the prescription next to the printed statement, “**DO NOT SUBSTITUTE**” and placing his or her initials next to the checked box. If the prescriber simply checks the “**DO NOT SUBSTITUTE**” box without initialing it, this could technically be considered creating an uncertainty in the mind of the pharmacist as to his or her responsibilities in filling the prescription with precisely the drug called for. Thus, if the absence of a prescriber’s initials following the check mark within a “**DO NOT SUBSTITUTE**” box creates either uncertainty or ambiguity in the mind of the pharmacist, then the pharmacist must contact the prescriber to ascertain exactly what the prescriber wants done.<sup>8</sup> This is if the prescription is provided as a hard copy. However, if the prescription is transmitted electronically either the prescriber can state, “Do Not Substitute” or he or she may check a box on the electronic prescription that is connected to a type-set “Do Not Substitute” statement. For an electronic prescription only a check mark in the box is required without the accompanying initial of the prescriber.<sup>9</sup>

## ***CAN HYPODERMIC NEEDLES AND SYRINGES STILL BE SOLD OVER-THE-COUNTER?***

The statutes regarding the sale of hypodermic needles and syringes over-the-counter for the use of insulin, epinephrine, and industrial use have now been altered as the result of legislation in 2004.<sup>10</sup>

In addition, the use of a hypodermic needle and syringe entry record book is no longer required.<sup>11</sup> Thus, a patient requiring insulin or epinephrine by subcutaneous injection may be required to have a prescription from a prescriber for the syringes and needles in order to administer these classes of drugs.

The amended statute (Calif. Business & Professions Code, Section 4145.5), does, however, note exceptions when the pharmacist may provide syringes and/or needles to a patient without a prescription under any of the following circumstances:<sup>12</sup>

- (1) "The person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment,"<sup>13</sup> or
- (2) "As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other blood-borne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, a physician or pharmacist may, without a prescription or a permit, furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older, and a person 18 years of age or older may, without a prescription, obtain 30 or fewer hypodermic needles and syringes solely for personal use from a physician or pharmacist."<sup>14</sup> Such a public health measure must be pursuant to authorization by a county or a city government mandate and registration with a local

health department in the Disease Prevention Demonstration Project (DPDP). If a pharmacy does wish to participate in the DPDP, the following must occur:<sup>15</sup>

- a) The pharmacy must register with the city or county Health Department,
  - b) The pharmacy must certify that it will provide purchaser with written information or verbal counseling on how to access drug treatment, testing, and treatment for HIV and Hepatitis C, and how to dispose of the used needles and syringes.<sup>16</sup> Section 4145.5[e] further suggests how pharmacies can provide needle and syringe recipients with safe disposal methods: a) provide an onsite collection and disposal program; b) provide mail-back to pharmacy sharps containers; or c) furnish to the recipient a sharps container to return to the pharmacy.
  - c) Storage by the pharmacy of hypodermic needles and syringes so that they are available only to authorized personnel, and
  - d) Provide proper disposal containers for used syringes and needles.
- (3) "A pharmacist may, without a prescription, furnish hypodermic needles and syringes for use on animals... providing that no needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity."<sup>17</sup>
- (4) "A pharmacist may now sell hypodermic needles and syringes without a prescription for uses that the Board determines are industrial."<sup>18</sup> (The Board will therefore need to provide in the future some clearer guidelines as to what will be allowable industrial use.)



In the past, as noted above, when hypodermic needles and syringes were sold over the counter, the pharmacy had to maintain a log book to enter the patient's and doctor's name, the type and number of syringes and needles provided, the time of the transaction, and the purpose. This is no longer required.

### ***WHAT IS THE STATUS OF POISONS SOLD BY A PHARMACY?***

Quite a number of years ago, it was not uncommon for pharmacists to sell specific poisonous substances for a therapeutic purpose. Substances like strychnine, mercuric oxide, arsenic, and boric acid were some of the common poisonous therapeutic agents sold in pharmacies. These and a number of other therapeutically dangerous agents were classified in schedules (Schedules A, B, and C) for control purposes and when bought in a pharmacy required that the purchaser sign a poison registry book, much like what was done with the OTC Hypodermic Registry Book. This is no longer the case today, at least in California, primarily because many of these poisonous substances have been replaced with safer and generally more effective drug substances. As a result the so-called "Poison Schedules" in California no longer exist, and many of these substances have fallen by the wayside.<sup>19</sup> They are generally no longer sold in pharmacies, with the occasional exception of boric acid.

Today, the pharmacist and the pharmacy in California are treated no differently than any other retail business that sells an item that may be poisonous in nature. Although pharmacists are subject to the same civil and criminal laws as any other merchant if a sale of such a substance is made with improper judgment (e.g. selling a poisonous substance like airplane glue to a minor), the pharmacist would most probably be held to a higher standard of care, and potentially more culpable, based upon his or her training, skill, and experience.

**MAY SAMPLE PRESCRIPTION DRUGS BE STORED  
AND DISPENSED FROM A PHARMACY?**

According to the federal laws, "No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample."<sup>20</sup> While a licensed prescriber may receive prescription drug samples from a manufacturer or drug company representative, a pharmacist or pharmacy is restricted from the receipt or dispensing of prescription drug samples directly from a manufacturer, wholesaler, or distributor of drugs.<sup>21</sup> There is however, a provision within the federal laws that will allow the transfer of a sample drug from a health care entity to a to another health care professional or entity such as a retail pharmacy for dispensing to patients provided the health care entity is acting at the direction and under the supervision of a licensed prescriber. The manufacturer or authorized distributor of a drug sample subject to the direction of a licensed prescriber may distribute drug samples by mail or common carrier to a pharmacy, if the request by the prescriber:<sup>22</sup>

- Is in response to a written request for drug samples made on a form which meets the requirement that the health care professional (e.g. pharmacist) will act at the direction and under the supervision of the requesting licensed prescriber.
- Is under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

State law allows for a physician assistant, nurse practitioner, certified nurse midwife, or a naturopathic doctor to sign for the request and receipt of complimentary prescription drug samples, if authorized to do so in a written protocol by the prescriber.<sup>23</sup>

***WHAT IS DMSO AND HOW MUST IT  
BE HANDLED BY THE PHARMACY?***

“DMSO” or dimethyl sulfoxide is an organic solvent that is not available by any drug manufacturer as an F.D.A. approved drug. It had its claim to fame during the 1970s and early 1980s as a substance used in the management of arthritis by topical application. The chemical has an extremely high absorption index when applied to the intact skin that allows it to attain relatively significant blood levels within a short period of time. Because of the controversy surrounding this agent (primarily the blood dyscrasias that it allegedly causes), the only available supply sources were and are through chemical supply companies.

Prescribers are still allowed to prescribe DMSO at the risk of it not being FDA approved for the management of arthritic conditions. While prescribers would be held to provide a patient an informed consent to sign describing the risks v. benefits of DMSO and other noted effects from the chemical, pharmacies who wish to dispense the drug pursuant to a prescriber's prescription would not be required to have the patient sign an informed consent at the pharmacy, and would have to order the chemical agent from a chemical supply dealer. If the pharmacy was to dispense DMSO pursuant to a prescriber's prescription order, the pharmacy would be responsible for the following additional labeling:<sup>24</sup>

- A label affixed to the DMSO container stating, “Warning: DMSO may be hazardous to your health. Follow the directions of the physician who prescribed the DMSO for you.”
- The label of any retail package of DMSO shall include appropriate precautionary measures for proper handling and first aid treatment and a warning statement to keep the product out of the reach of children.

**MAY A CLINIC INSTALL AN  
AUTOMATED DRUG DELIVERY SYSTEM?**

Automated drug delivery systems may now be located in specified clinics. These clinics would be required to develop and implement written policies and procedures regarding the use, maintenance, and security of these systems, and such policies and procedures shall be maintained at the location where the automated drug system is being used.<sup>25</sup> Furthermore, a pharmacist must consult with the patient via a telecommunications link with two-way audio and video capabilities.<sup>26</sup> It would be required that the pharmacist review the prescription and the patient profile before releasing the prescription drug or devices from the automated drug delivery system.<sup>27</sup> In addition, the pharmacist must be in California while involved in the operation of this automated drug delivery system; and the pharmacist would be responsible for the stocking, inventory control, and review of the operation and maintenance of the system.<sup>28</sup>

The pharmacist shall also be responsible for an inspection of the drugs in the automated drug delivery system, the cleanliness of the machine, and to review all transaction records to verify the security and accountability of the system. This inspection is to occur once monthly.<sup>29</sup>

**MAY A SKILLED NURSING FACILITY AND  
INTERMEDIATE CARE FACILITY INSTALL AN  
AUTOMATED DRUG DELIVERY SYSTEM?**

A pharmacy may provide services to a skilled nursing facility or a intermediate care facility through the use of an automated drug delivery system. If an automated drug delivery system is to be used in these facilities, the system requires the following:<sup>30</sup>

- The system must be under the supervision of a pharmacist.

- That policies and procedures be created that ensure the safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. The policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.
- The policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.
- Pursuant to the policies and procedures an emergency drug may be retrieved from an automated drug delivery system pursuant to an order by a prescriber for immediate administration to a patient. Within 48 hours the drug order shall be reviewed by a pharmacist.
- Drugs removed from an automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.
- A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient.
- Access to the automated delivery system shall be controlled and tracked using an identification or password system or biosensor.
- The automated drug delivery system shall make a complete and accurate record of all transactions involving accessing system, adding drugs, or removing drugs from the system.
- There shall be training of personnel who will use the automated delivery system.
- The system, however, does not require the pharmacist to be physically present if the pharmacist surveys the system electronically.
- The pharmacy is responsible for the stocking, upkeep, and general monitoring of the system.



***WHAT IS REQUIRED OF A PHARMACIST OR  
PHARMACY IN THE HANDLING AND  
FURNISHING OF RADIOACTIVE DRUGS?***

A pharmacist involved in the handling and especially the preparation of radioactive drugs must be specifically trained in these areas.<sup>31</sup> This requires that such a pharmacist has completed a nuclear pharmacy course and/or has gained experience in related programs approved by the Board of Pharmacy.

Title 16, California Code of Regulations (CCR), Section 1708.5 reads in pertinent part, "A pharmacy furnishing radioactive drugs is any area... described in a permit issued by the Board of Pharmacy where radioactive drugs are stored, processed, compounded, repackaged, or dispensed. A pharmacy exclusively furnishing radioactive drugs shall be exempt from the patient consultation area requirements... unless the Board of Pharmacy finds otherwise."<sup>32</sup> A pharmacist qualified to furnish radioactive drugs shall be in the pharmacy whenever the furnishing of radioactive drugs occurs.

***ARE THERE LIMITS ON EMERGENCY DRUG  
SUPPLIES AS WARD STOCK IN LICENSED  
HEALTH CARE FACILITIES?***

A list of emergency supplies including drugs and medical devices determined to be needed shall be approved by the health care facility's patient care policy committee or pharmacy services committee. Such policy pertaining to the specific drugs or medical devices to make up the emergency supply and their quantities shall be made available to each nursing station within the facility.<sup>33</sup> The emergency drug and medical device supplies ordered for a specific patient care area shall be placed in secured storage areas.<sup>34</sup> These emergency drug supplies shall be readily available to each nursing station and kept in a secure place. Section 1261.5 of

the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to 48 at any given time.<sup>35</sup> The State Department of Public Health, based upon a review, has the authority to limit the number of doses of each drug available as an emergency supply in a sealed container for a given patient care area to not more than 16 doses of any separated drug dosage form if the Department believes that amount is appropriate.<sup>36</sup>

Not more than four of the 48 oral form or suppository form drugs secured for storage in the emergency supplies container shall be psychotherapeutic drugs – this requirement can be overridden to increase to 10 psychotherapeutic drugs subject to the Department of Public Health's approval based upon the needs of the patient population at the facility.<sup>37</sup>

The policy and procedures should also state that there will also be routine inspection of these storage areas by the pharmacy to ensure that all drug and medical device supplies are properly stored and accounted for, and that any outdated drugs are removed from and replaced to the stock supplies. Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years.<sup>38</sup>

***WHAT STANDARDS MUST BE FOLLOWED IN THE USE  
OF AN AUTOMATED DRUG DELIVERY SYSTEM (ADDS)  
IN A COMMUNITY PHARMACY SETTING?***

The quantities of drugs noted above as part of an emergency supply as ward stock shall not apply to an "automated drug delivery system" (also referred to as ADDS) which is defined as a mechanical system that provides for storage and dispensing of drugs.<sup>39</sup> The stocking and control of the ADD System will be under the control of

the facility's pharmacy department. The ADD System shall accurately account for all drugs dispensed, and all records of drug distribution from these machines shall be maintained within the facility for a minimum of three years.<sup>40</sup> The pharmacy and the facility shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and quality of drugs being stored and dispensed.<sup>41</sup>

If the ADD System is to be used as an emergency drug supply unit, drugs dispensed from the System shall be limited to a 72 hour supply or less.<sup>42</sup> The drugs shall be dispensed only upon authorization of a pharmacist and shall be properly labeled.<sup>43</sup> The labeling requirement shall not be subject to the same standards of a usual prescription label if the drugs are in unit dose packaging or unit of use packaging and patient information regarding the dispensed drug is readily available at the time of the drug being provided to the patient.<sup>44</sup> The stocking of the ADD System shall be performed by a pharmacist, and the preparation of drugs in packets to be placed in the ADD System may be done outside of the patient care facility.<sup>45</sup> The review and maintenance of the ADD System shall be done monthly by the pharmacist and shall be specifically directed to doing:<sup>46</sup>

- A physical inspection of the drugs contained in the ADD System.
- Any necessary cleaning to maintain the cleanliness of the System.
- A review of all transaction records to validate the security and accountability of the System.

A facility that uses an ADD System is required to notify the Department of Public Health Services (DPHS) in writing prior to using the System and describe the System design, the personnel who will have access to the System, the policies and procedures covering staff training regarding the use and maintenance of the System, in addition to drug accountability and security methods.<sup>47</sup> The DPHS has the authority to revoke the use of an ADD System if it

determines that a facility is not in compliance with the requirements of the statute.<sup>48</sup>

***MAY REFILL PRESCRIPTIONS BE STORED IN  
SECURED CONTAINER UNITS IN A PHARMACY  
TO BE PICKED-UP BY PATIENTS WITHOUT A  
PHARMACIST'S INTERVENTION?***

A community pharmacy may install security containers or boxes within close proximity to the pharmacy area to allow patients to drop-off their prescriptions (new and refillable) whether the pharmacy is open or closed.<sup>49</sup> The pharmacy providing this means in which patients may drop-off or pick up specifically prescriptions that have been previously refilled where there is no requirement for a pharmacist's consultation the following must occur:<sup>50</sup>

- Each patient desiring to drop-off or pick-up their prescription from a security box must sign a written consent to participate in this service.
- The pharmacist will determine that each patient using the security box meets inclusion criteria spelled out in the pharmacy's policies and procedures prior to allowing the patient access to his or her refill prescription using the security box. No prescription is to be released to a patient using the security box if the pharmacist determines that such patient requires counseling on the medication being refilled and dispensed.
- The security boxes installed must have a means to identify each patient and only release that patient's prescription.
- The security boxes are secure from access and removal by unauthorized individuals.
- The pharmacy is responsible for the prescription medications stored in the security boxes.
- Any incident involving the security box where there is a patient complaint, product error or omission in filling the medication in a reasonable time and manner shall be

reviewed in accordance with the pharmacy's quality assurance program.

- There are written policies and procedures regarding the security boxes that covers:<sup>51</sup>
  - Maintaining the security of the delivery device.
  - Determining and applying inclusion criteria regarding which medications are appropriate for placement into the security boxes, and withholding placement based upon a need to consult with the patient.
  - Notifying patients that consultation with a pharmacist is always available even though the prescription was refillable and adjudged by the pharmacist that no consultation was necessary.
  - Assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the security boxes.
  - Orienting participating patients on the use and purpose of the security boxes.
  - Ensuring the delivery of medications to patients in the event the security boxes are disabled or malfunctions.
- All written policies and procedures pertaining to the use, maintenance, and security of these security prescription boxes shall be maintained at least three years beyond the last use of a security box delivery system.<sup>52</sup>

Each security box identified for a specific patient will have a code system whereby only that patient or his or her representative may enter the box to acquire the refill prescription. It is important to keep in mind and to emphasize that these security boxes for prescription drugs are to be used for the delivery of prescriptions to patients that are refills and where there is no need or requirement that the patient receive a consultation upon the dispensing of the refill medication.



### ***CAN VETERINARY DRUGS STILL BE DISPENSED WITHOUT A PRESCRIPTION?***

In the past veterinary drugs were excluded from the category of "dangerous drugs." The law now authorizes a licensed veterinarian to prescribe a dangerous drug and authorizes the Veterinary Medical Board to enforce the provisions of the Pharmacy Law to include this category of drugs as dangerous drugs and thus requires a prescription in order for them to be dispensed.<sup>53</sup>

### ***WHAT ARE THE PRESENT STANDARDS FOR VETERINARY FOOD-ANIMAL DRUG RETAILERS?***

A retailer, other than a pharmacy, engaged in the sale of veterinary food-animal drugs must have a permit issued by the California State Board of Pharmacy.<sup>54</sup> While a pharmacy does not require additional permits from the Board, an ordinary retailer wishing to sell these veterinary items must meet certain requirements for registration as a "veterinary retailer exemptee" (also being referred as a "designated representative" or if in charge, a "representative-in-charge"). The requirements are as follows:<sup>55</sup>

- He or she must fill out an application with the Board of Pharmacy to register as a veterinary food-animal drug retailer.
- He or she shall be a high school graduate or possess equivalent education.
- He or she shall have one year of paid work experience related to the distribution or dispensing of dangerous drugs.
- He or she must complete a training course approved by the Board.

There are a series of other standards applied to Veterinary Food-Animal Drug Retailers that must be followed:<sup>56</sup>

- The veterinary food-drug retailer pursuant to a prescription from a veterinarian shall fill prescriptions for food-producing animals.
- When a veterinary retailer exemptee (or designated representative) dispenses a prescription for a controlled substance, the labels of the container shall be countersigned by the prescribing veterinarian before being dispensed.
- The veterinary retailer exemptee (or designated representative) may refill prescriptions allowed to be refilled if the veterinarian has indicated that they are to be refilled.
- The veterinary retailer may not refill a veterinarian's prescription order six months after the issuance date of the initial order. Records of prescriptions shall be kept for 3 years after the last recorded filling of the prescription.
- If a veterinary retailer is unable at any one time to fill the full quantity of drugs prescribed, the retailer may partially ship a portion as long as the full quantity is shipped within 30 days. Any shipment after the 30 day period will require a new prescription. For each date the prescription is shipped, the retailer must indicate on the prescription each date the drugs are shipped, quantity shipped, and the number of containers shipped.
- If a employee who has been certified as an exemptee leaves the employ of a veterinary food-animal drug retailer, the retailer shall immediately return the certificate of exemption to the Board of Pharmacy.

#### ***MAY A PHARMACIST DISPENSE REPLACEMENT CONTACT LENSES?***

A pharmacist may dispense replacement contact lenses pursuant to a valid prescription from a physician or

optometrist.<sup>57</sup> If the pharmacist is to dispense replacement contact lenses, the following must occur:<sup>58</sup>

- The replacement contact lenses must conform to state and federal statutes governing such prescriptions.
- The prescription must contain the state license of the prescribing practitioner.
- The label affixed to the prescription container must explicitly state an expiration date of not more than one year from the date of the last prescribing examination.
- The prescription must explicitly state that it is a prescription for contact lenses and include the lens brand name, type and tint, and other specifications necessary for ordering lenses.
- The prescription dispensed must be for the exact contact lenses ordered and not for any substitutions.
- The pharmacist shall direct the patient to confer with his or her eye-care practitioner in the event of any problems or reactions to the lenses.
- The pharmacist upon dispensing the lenses shall provide to the patient the following written notice:

*“Warning: If you are having any unexplained eye discomfort, watering, vision change, or redness – remove lenses immediately and consult with your eyecare practitioner.”*

- The pharmacy, before dispensing replacement contact lenses, shall register with the Medical Board of California at the time of initial application for license.

All nonresident pharmacies shall keep records of lens prescriptions shipped, mailed, or delivered to persons in California for 3 years and such records shall be made available to the Medical Board of California for inspection upon request.<sup>59</sup>

***MAY A PHARMACY FURNISH PRESCRIPTION  
DRUGS TO HOME HEALTH AGENCIES AND  
LICENSED HOSPICES?***

A pharmacy may furnish to a licensed home health agency and/or hospice dangerous drugs for parenteral therapy other than controlled substances. Such drugs must be in a portable container when the drugs are furnished to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.<sup>60</sup> The pharmacy furnishing such drugs in a portable container must ensure the following:<sup>61</sup>

- That the portable container is furnished by a pharmacist.
- That the container is sealed with a tamper-proof seal that must be broken to gain access to the drugs.
- That the sealed container is under the control of the pharmacist, nurse, or delivery person at all times when not in the pharmacy.
- That the container bears a label on the outside with a list of the contents.
- That the sealed container is maintained at proper temperatures according to U.S.P. standards.
- The container may contain the following drugs:<sup>62</sup>
  - 1000 ml. of 0.9% sodium chloride intravenous solution in containers of a size determined by the pharmacy.
  - 1000 ml. of 5% dextrose I.V. solution in containers of a size determined by the pharmacy.
  - Two vials of urokinase 5000 units.
  - Up to 5 heparin sodium lock flush 100 units/ml.
  - Up to 5 heparin sodium lock flush 10 units/ml.
  - Up to 5 epinephrine HCl solutions 1:1000.
  - Up to 5 epinephrine HCl solutions 1:10,000.
  - Up to 5 diphenhydramine HCl 50 mg/ml.
  - Up to 5 methylprednisolone 125 mg/2ml.
  - Up to 5 normal saline (up to 30 ml vials).
  - Up to 5 naloxone 1 mg/ml, 2 ml.

- Up to 5 droperidol 5 mg/2ml.
- Up to 5 prochlorperazine 10mg/2ml.
- Up to 5 promethazine 25 mg/ml.
- Up to 5 dextrose 25 gms/50 ml.
- Up to 5 glucagon 1 mg/ml.
- Up to 5 insulin (human) 100 units/ml.
- Up to 5 bumetamide 0.5 mg/2ml.
- Up to 5 furosemide 10 mg/ml.
- Up to 5 EMLA Cream 5 gm tubes.
- Up to 5 lidocaine 1% 30 ml. vials.

Before the home health agency or hospice is issued the portable container with any of the drugs listed above, it will be required that such agencies have written policies and procedures that:<sup>63</sup>

- State methods of storage of the portable container as well as methods of transfer between the pharmacy and the agency.
- State the method in which a drug from the container is to be furnished according to the written or oral authorization of a prescriber.
- State a specific treatment protocol for the administration of each medication contained in the portable container.
- Are reviewed and revised (as needed) annually by a group of professional personnel including a physician, a pharmacist, and a registered nurse.

A copy of such policies and procedures, along with protocols shall be maintained by the furnishing pharmacy.<sup>64</sup>

Where a drug from the container has been administered to a patient pursuant to an oral order from a prescriber, the pharmacy shall ensure that the oral order is immediately written down by the nurse or pharmacist and sent within 24 hours (by written copy or fax) to the furnishing pharmacy. The prescriber must then forward within 20 days a signed copy of the drugs ordered to the furnishing pharmacy.<sup>65</sup>



Once the seal has been broken on the portable container for the purpose of administering drugs to agency patients, the agency's nurse shall return the container to the furnishing pharmacy within 7 days after the seal has been broken. The furnishing pharmacy will then perform an inventory of the drugs used from the container, and if the container is to be reused, the pharmacy must restock and reseal the container before it is again furnished to the home health agency or hospice.<sup>66</sup> If the container is not used within 60 days of its being furnished to the agency, the agency must return the sealed container to the pharmacy for verification of product quality, quantity, integrity and expiration dates. The furnishing pharmacy shall also have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.<sup>67</sup>

The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.<sup>68</sup>

#### ***WHAT NEW REQUIREMENTS ARE THERE INVOLVING THE SALE OF PRODUCTS CONTAINING DEXTROMETHORPHAN?***

The sale of products containing dextromethorphan can only be sold to persons 18 years or older. Proof of age will be required to be shown by the purchaser. Bona fide evidence of age and identity from the purchaser can be produced by showing a document issued by a federal, state, county, or municipal government, or agency including but not limited to, a motor vehicle operator's license, a California state identification card, an identification card issued to a member of the Armed Forces, or other form of identification that bears the name, date of birth, description, and picture of the person.<sup>69</sup>

It is suggested that a retail business that sells products containing dextromethorphan over-the-counter utilize a cash register that is equipped with an age-verification feature to monitor age-restricted drug products in order to direct the retail clerk making the sale to request proper identification.<sup>70</sup>

A violation by a retailer who sells dextromethorphan products inappropriately would subject that retailer to a fine not to exceed \$250.<sup>71</sup>

### ***WHAT RESTRICTIONS EXIST REGARDING THE SALE OF EPHEDRINE-LIKE PRODUCTS?***

On March 9, 2006, as part of Title VII of the USA Patriot Improvement and Reauthorization Act of 2005 (Public Law 109-177), congress signed into law The Combat Methamphetamine Epidemic Act (CMEA) of 2005. This law further regulates the over-the-counter sales of ephedrine, pseudoephedrine and phenylpropanolamine products. This federal law has various components that set-up more stringent requirements than state laws statutes or regulations. However, if the state law is more stringent on certain points regarding the control of ephedrine-like products than the federal law, the state law will preempt the federal law on those certain points.<sup>72</sup>

The new federal law became enforceable on September 30, 2006 with requirements that any retailer involved in the sale of an ephedrine-like product over-the-counter must be "self-certified;" provide employee training regarding the nature, storage and sale of these products; store these products in controlled and secure areas; require patient photo identification; maintain logbooks accounting for all sales transactions of these products; and ensure that there is legitimate use among purchasers who are 18 years or older.

"Self-certification" (is location-specific and not employee-specific) involves the retailer who wishes to sell

these products to register on line at [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov) and providing the following information:<sup>73</sup>

- DEA number (if applicable).
- Tax I.D. number.
- Business name, address, city and state, and zip code.
- Person to be contacted, telephone number and e-mail address.
- Number of employees at location, and those to be trained.
- Type of establishment (e.g. pharmacy, grocery, etc.).
- Ephedrine-like products to be handled.

The DEA has prepared the necessary training materials for those retail vendors participating in the sale of ephedrine-like products. These materials can be ordered on the following web site: [www.deaaddiversion.usdoj.gov/meth/index.html](http://www.deaaddiversion.usdoj.gov/meth/index.html). Additional training materials prepared by the retailer may also be used. However, the DEA's materials must be incorporated in the training program. Records must be kept on all training programs undertaken for employees.<sup>74</sup>

All retailers selling ephedrine, pseudoephedrine, or phenylpropanolamine must store these drugs either behind the counter or in a locked cabinet. A logbook (either written into or held electronically) must be maintained to record all sales of these ephedrine-like products. The following information must be entered into the logbook:<sup>75</sup>

- Name of product, strength and quantity sold.
- Customer must enter into the logbook the following:
  - Customer name, address, date, and time of sale.
  - Customer signature.

The purchasing customer must show a photo identification either issued by a state or the federal government. While the federal government via the CMEA legislation does not impose any age restrictions, California requires that the consumer of these products be 18 years of age or older.<sup>76</sup>

Daily and monthly purchase and sales limits are set by the CMEA. The following represent those limits:<sup>77</sup>

- Daily sales limit per customer regardless of the number of transactions – 3.6 grams.
- Monthly sales limit per customer – 9 grams.

Contrary to California state law, the requirements of the federal CMEA apply to all formulations of scheduled listed chemical products containing ephedrine, pseudoephedrine, or phenylpropanolamine. This law applies to all solid oral forms of these ephedrine-like drugs as well as gel capsules, liquids and children formulations.<sup>78</sup> It is however important to note that under the federal law that if a person purchases a single package containing 60 mgs of pseudoephedrine (one 60 mg or two 30 mg tablets) the purchaser does not have to provide identification or sign the logbook. This exception does not apply to ephedrine or phenylpropanolamine even if single doses are purchased. Then identification and the signing of the logbook are required.<sup>79</sup>

California law, that needs to be amended to be consistent with the federal law, still maintains a limit on the sale of ephedrine-like products by either a pharmacy or any other retail operation that chooses to sell such products containing ephedrine or pseudoephedrine to 3 packages or 9 grams per transaction.<sup>80</sup> Excluded from this requirement under California law are liquid pediatric products for children provided the liquid dose does not exceed 15 mgs per 5 ml of liquid, and such liquid products are intended for administration to children under two years of age where the dosage unit does not exceed two mls and the total package content does not exceed one fluid ounce.<sup>81</sup> Prescription sales of these ephedrine-like products that exceed the 3 package or 9 gram limit should be reported to the State Department of Justice.<sup>82</sup> This California law is in conflict with the more stringent federal CMEA law. Thus, California retail operations must follow the stricter federal law. However, California law is consistent with the federal law making it

unlawful for a retail operation to sell, transfer, or otherwise furnish these ephedrine-like substances to a person under 18 years of age.<sup>83</sup>

Those retail operations, such as food markets, not licensed by the California Board of Pharmacy or Department of Public Health Services (DPHS) who wish to continue to sell ephedrine-like products may do so and are held to the same standard of not exceeding sale limits as described above. To exceed the OTC sale limit of these products may either be charged with a misdemeanor or a felony.<sup>84</sup>

All supplemental agents containing ephedrine or an ephedrine-like agent have been removed from the over-the-counter market. The FDA issued the following "Ban On Ephedra" report on February 6, 2004:<sup>85</sup>

"Ephedra will no longer be legal for sale in the US to take effect April 12, 2004. The ban on ephedra does not pertain to traditional Chinese herbal remedies nor to products like herbal teas that are regulated as conventional foods. Acupuncturists, herbalists and other practitioners or Oriental medicine will still be allowed to dispense teas, pills and powders containing ephedra for the purpose of treating colds, asthma, persistent cough, headache, water retention and other maladies. Dispensing ephedra for the purpose of weight loss, muscle building and athletic performance will be prohibited."

#### ***WHAT RESTRICTIONS EXIST REGARDING THE SALE OF CERTAIN IODINE CONTAINING PRODUCTS?***

As a result of the concerns for purchasing ephedrine-like products for the purpose of converting it to methamphetamine, whereupon iodine is one of the necessary ingredients to aid in that conversion, restrictions have been



placed on the over-the-counter sale of certain strengths of iodine containing products. According to California law it is unlawful for any retailer to sell, transfer, or furnish over-the-counter any betadine or povidone solution with iodine content in excess of one percent (1%) or where the 1% betadine or povidone content is in a container greater than eight (8) ounces. Tincture of iodine may not exceed two percent (2%) or be sold as a 2% solution in containers greater than one (1) ounce.<sup>86</sup> If such iodine products exceed the contents and volumes noted above and are to be sold, transferred, or furnished over-the-counter, they will require the provider to submit a report to the Department of Justice of all such transactions.<sup>87</sup>

***MAY EPINEPHRINE AUTO-INJECTORS BE  
FURNISHED TO A SCHOOL DISTRICT BY A  
PHARMACY?***

A pharmacy is presently authorized to furnish epinephrine auto-injectors to a school district or county office of education. In order to furnish this drug product, there must be a written order from a prescriber specifying the amount to be furnished. The school district or county office of education must maintain records for 3 years regarding the use of such epinephrine auto-injectors. The pharmacy must also keep records of the provision of the drug pursuant to an order for three years.<sup>88</sup>

***MAY PRESCRIPTION DRUGS THAT ARE RETURNED BY  
A PATIENT TO THE PHARMACY BE RESOLD BY THE  
PHARMACY?***

Once a prescription drug is filled and dispensed to a patient, and the patient has it in his or her possession, regardless of the time they have held on to it and regardless if the drug is still in an original drug package, the California

state laws will declare that that drug cannot be reused and re-dispensed to another patient.<sup>89</sup> The rationale for disallowing prescription drugs to be reused in this manner is predicated on the fact that the pharmacist would no longer have assurances that the drug was not tampered with or stored properly. Pharmacists certainly have the right to take prescription drugs back from patients and reimburse them for what they paid only as a good faith measure, but are obligated to destroy the drug once taken back and not to reuse it for a subsequent prescription.<sup>90</sup>

#### ***WHAT NEW RULES NOW EXIST FOR THE REDISTRIBUTION OF UNUSED PRESCRIPTION DRUGS FOR INDIGENT PATIENTS?***

Rules have been established to provide for medically indigent patients needing access to prescription drugs where such drugs would be provided at no cost to the indigent patient. These prescription drugs would be acquired from a surplus voluntary drug repository created by donations of such drugs by pharmacies, skilled nursing facilities, wholesalers, and county facilities.<sup>91</sup>

Regarding county-owned pharmacies or those pharmacies that have contracted with the county for providing free prescription drugs to the indigent population, these pharmacies at a minimum must:<sup>92</sup>

- Establish eligibility for medically indigent patients who may participate in the program.
- Not charge these patients for this category of prescribed medications.
- Develop a formulary of the medications that will be used in this program.
- Ensure proper safety and management of any medications collected by and maintained under the authority of a county-owned or county-contracted, licensed pharmacy.

- Ensure the privacy of individual's for whom the medication was originally prescribed.

Further, any donated medication to the county must:<sup>93</sup>

- Not be a controlled substance, nor have been adulterated, misbranded or stored contrary to USP or manufacturer standards.
- Not have been in the possession of a patient, and only under the control of the medical staff if donated by a skilled nursing facility.
- Be donated only if in an unopened, tamper-evident package or modified unit dose container.
- Be maintained in the donated packaging units until dispensed to an eligible patient who presents a valid prescription. The medication will then be dispensed in a new and properly labeled container.
- Be segregated from the pharmacy's other drug stock.
- Not be dispensed if expired.

The pharmacy must keep acquisition and disposition records of the donated medications, and protocols must be established for the packaging, transporting, storing, and dispensing of medications that require refrigeration.<sup>94</sup>

### ***MAY MERCURY FEVERY THERMOMETERS STILL BE SOLD OVER-THE-COUNTER?***

Effective July 1, 2002, mercury fever thermometers may only be furnished to a requesting customer pursuant to a prescription.<sup>95</sup>

**WHAT IS PHARMACY'S RESPONSIBILITY  
IN PROVIDING "SHARPS CONTAINERS"  
TO PATIENTS?**

On September 1, 2008 the State's Legislature made it illegal to dispose of sharps waste by throwing such items in the usual trash or recycling containers.<sup>96</sup> By definition, "sharps waste" involves "any device having acute rigid corners, edges, or protuberances capable of cutting or piercing" – such items as hypodermic needles and syringes, blades, blood vials contaminated with biohazardous waste, or other waste-contaminated items that are capable of cutting or piercing the skin or other parts of the body fall within this category.<sup>97</sup> Products of the nature described are to be placed in "sharps containers" that are defined as "rigid puncture-resistant containers that, when sealed, are leak resistant and cannot be reopened without great difficulty."<sup>98</sup> These sharps containers are to be brought to collection centers coordinated and identified by the California Integrated Waste Management Board. Pharmacies are to be among these collection centers.<sup>99</sup> The law now defines that pharmacies may accept the return of needles and syringes from the public if contained in a sharps container.<sup>100</sup> Pharmacies that presently participate in receiving sharp containers from patients will need to follow the policies of disposal set forth by the California Integrated Waste Management Board. Regarding sites available for hypodermic needle/syringe disposal one may go to the following website: [www.ciwmb.ca.gov/HHW/HealthCare/Collection](http://www.ciwmb.ca.gov/HHW/HealthCare/Collection) for disposal information.

REFERENCES TO CHAPTER 10

1. Calif. Bus. & Prof. Codes, Sec. 4073[a]
2. *Ibid.* at Sec. 4073[a]
3. *Ibid.* at Sec. 4073[c][e]
4. *Ibid.* at Sec. 4073[e]
5. *Ibid.* at Secs. 4052.5[a][b]
6. *Ibid.* at Sec. 4052.5[a]
7. *Ibid.* at Sec. 4073[b]
8. *Ibid.* at Sec. 4073[b]
9. *Ibid.* at Sec. 4073[h]
10. Passage of Calif. Senate Bill 1159 in 2004
11. Repeal of Calif. Bus. & Prof. Code, Sec. 4146
12. *Ibid.* at Sec. 4145.5
13. *Ibid.* at Sec. 4145.5[a]
14. *Ibid.* at Sec. 4145.5[b]
15. *The Script*, Oct. 2005, pg. 9
16. Calif. Bus. & Prof. Code, Sec. 4145.5[e]
17. Calif. Bus. & Prof. Code, Sec. 4145.5[c]
18. *Ibid.* at Sec. 4144.5[a]
19. *Ibid.* at Sec. 4240
20. 21 U.S.C., Sec. 353[c][1]
21. *Ibid.* at Sec. 353[d][1][2]
22. *Ibid.* at Sec. 353[d][2][A]
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24. *Ibid.* at Sec. 4077[d][e]
25. *Ibid.* at Sec. 4186[a]
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28. *Ibid.* at Sec. 4186[c][f]
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32. *Ibid.* at Sec. 1708.5
33. Calif. Bus. & Prof. Code, Sec. 4119[a]
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35. *Ibid.* at Sec. 1261.5[a]



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37. *Ibid.* at Sec. 1261.5[b]
38. *Ibid.* at Sec. 4119[b][5]
39. *Ibid.* at Sec. 1261.5[c]
40. *Ibid.* at Sec. 1261.6[a][b]
41. *Ibid.* at Sec. 1261.6[d]
42. *Ibid.* at Sec. 1261.6[e][1]
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50. *Ibid.* at Sec. 1713[d]
51. *Ibid.* at Sec. 1713[e]
52. *Ibid.* at Sec. 1713[f]
53. Calif. Bus. & Prof. Code, Sec. 4042
54. *Ibid.* at Sec. 4196[a][b] & Title 16, Calif. Code of Regs., Sec. 1780.1
55. Calif. Bus. & Prof. Code, Secs. 4053, 4196[c] and 4201[a], & *The Script* (Publication of the Calif. State Board of Pharmacy), Feb. 1997 Edition.
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99. The *Script* (Publication of the Calif. State Board of Pharmacy, Feb. 2009 Edition, pg. 6 & Calif. Bus. & Prof. Code, Sec. 4146
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## CHAPTER 11

# COMPOUNDING AND MANUFACTURING ISSUES IN PHARMACY PRACTICE

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## **INTRODUCTORY COMMENT REGARDING COMPOUNDING**

The two subject headings that follow this introduction have to do with *general drug compounding requirements* or “non-sterile compounding” that does not require separate licensing by the Board of Pharmacy; and *sterile drug compounding requirements* that does require separate licensing by the Board.

Subsequent sections to this chapter address factors that separate compounding from the FDA’s concerns that drug compounding may infringe on drug manufacturing practices. Two other later sections dealing with compounding drugs for a prescriber’s office use, and the compounding of drugs for future furnishing or dispensing.

The term “compounding unapproved drugs” specifically means the mixing of one or more drugs in a formulation prepared by the dispensing pharmacy and not necessarily recognized as an official drug formulation by the FDA. As an example, even if you compound or mix two official FDA recognized drugs together in a special formulation, the resultant mixture will be considered an “unapproved drug.”

## **GENERAL COMPOUNDING REQUIREMENTS TO BE MET BY A PHARMACY**

General compounding requirements that must be followed by all pharmacy operations were put into effect on July 6, 2010.<sup>1</sup> These requirements are in addition to the sterile compounding rules covered in Title 16, Calif. Code of Regulations, Sections 1751 through 1751.10:



**Meaning of Compounding:**<sup>2</sup> Compounding pursuant to filling a prescription shall mean:

- Altering the dosage form or delivery system of a drug.
- Altering the strength of a drug.
- Preparing a drug product from chemicals or bulk drug substances.

Not included in the definition of compounding:

- Reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration.
- Tablet splitting
- Addition of flavoring agents to enhance palatability.

**Compounding Limitations and Requirements:** As a general rule no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient. However, a pharmacy may prepare and store a limited quantity of a compounded drug in advance of receipt of a patient-specific prescription where there is a documented history associated with that pharmacy of prescriptions for patients receiving that compounded prescription. This allowance of preparing amounts of a compounded drug in anticipation of yet-to-be identified patients is for the purpose of ensuring continuity of care for an identified population of patients receiving the same compounded product.<sup>3</sup>

Compounded medications can be requested for a prescriber's office use in reasonable quantities. A reasonable quantity is that amount of compounded drug that:<sup>4</sup>

- Is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, and is properly labeled for the patient.
- Is consistent with and is within the scope of that prescriber's practice.

A drug product shall not be compounded until the pharmacy has first prepared a written master formula

record that includes at least the following elements (where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself):<sup>5</sup>

- Active ingredients to be used.
- Inactive ingredients to be used.
- Process and/or procedure used to prepare the drug.
- Quality reviews required at each step in preparation of the compounded product.
- Post-compounding process or procedures required, if any.
- Expiration dating requirements.

Every compounded product by a pharmacy shall have an expiration date no longer than 180 days, or less if any of the product's ingredients expire before the 180 days.<sup>6</sup> Shorter expiration dates may be used if deemed appropriate in the professional judgment of the responsible pharmacist. .

Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the Board (form 17M-39 rev.).<sup>7</sup> That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. These sections shall be completed before July 1 of odd-numbered years, or within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license.<sup>8</sup>

Records of Compounded Drug Products):<sup>9</sup> For each compounded drug product, the pharmacy records shall include:

- The master formula record.
- The date the drug product was compounded.
- The identity of the pharmacy personnel who compounded the drug product.
- The identity of the pharmacist reviewing the final drug product.

- The quantity of each component used in compounding the drug product.
- The manufacturer and lot number of each component. If the manufacturer's name is unavailable, the name of the supplier may be substituted.
- The equipment used in compounding the drug product.
- A pharmacy assigned reference or lot number for the compounded drug product.
- An expiration date for the final compounded drug product.
- The quantity or amount of drug product compounded.
- The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, and components used in compounding, if such products are not approved by the F.D.A.
- Pharmacies shall maintain and retain all records noted above for at least three years from the date the record was created.

**Labeling of Compounded Drug Products:**<sup>10</sup> Additional information that is to be placed on the label of a compounded drug product shall contain:

- The generic name(s) of the principal active ingredient(s).
- A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
- Drug products compounded and placed in unit dose containers, that are too small for conventional labeling, shall at least be labeled with the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and an expiration date. Bar coding is now required if units of dose are prepared at a centralized hospital pharmacy area to be used at other hospitals.<sup>11</sup>

**Compounding Policies and Procedures:**<sup>12</sup> Any pharmacy engaged in compounding must maintain written policies and procedures that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other related operating procedures pertaining to compounding.

- Policy and procedures shall be reviewed on an annual basis by the pharmacist-in-charge and updated as needed.
- Policy and procedures shall contain the following:
  - Procedures for notifying staff assigned to compounding duties of any changes in processes or to general policies and procedures.
  - Documentation of a plan for recall of a dispensed compounded drug product.
  - Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures.
  - Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
  - Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

**Compounding Facilities and Equipment:**<sup>13</sup> It must be insured that any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications. Such equipment shall be properly calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records shall be maintained in the pharmacy.

**Training of Compounding Staff:**<sup>14</sup> A compounding pharmacy shall maintain written documentation demonstrating that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to drug compounding.

**Compounding Quality Assurance:**<sup>15</sup> A pharmacy engaged in compounding shall maintain, as part of its policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of all compounded products. All reports generated by the pharmacy shall be maintained and reviewed. The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards.

***WHAT NEW REGULATIONS ARE IN EFFECT  
FOR THE COMPOUNDING OF STERILE  
PRODUCTS PREPARED IN A  
COMMUNITY PHARMACY SETTING?***

As the result of an unfortunate situation where several individuals died because of contaminated sterile injectable products that were compounded and dispensed by a California community pharmacy, the Board has implemented a series of regulations that will hopefully prevent recurrence of this tragic event. Presently such extemporaneous preparation of sterile products by a community pharmacy must be separately licensed by the Board of Pharmacy on an annual basis.<sup>16</sup>



This license is not transferable and the license will only be issued to a pharmacy.<sup>17</sup> Furthermore, the license to compound injectable sterile drug products may be issued to the owner of the pharmacy license at that location and will not be issued until the location has been inspected by the Board.<sup>18</sup>

Pharmacies in hospitals, home care agencies, or skilled nursing facilities that are involved in the preparation of sterile injectable products are not under the same licensing requirement if they are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or other private accreditation agencies recognized by the Board such as the California Department of Public Health. These patient care entities are then exempt from the requirement to obtain a sterile injectable compounding license from the Board of Pharmacy.<sup>19</sup>

Any pharmacy that inappropriately compounds sterile products where there is a potential threat to the health and welfare of the public will be susceptible to an immediate cease and desist order issued by the Board of Pharmacy.<sup>20</sup> The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.<sup>21</sup> The issuance of a cease and desist order will allow the owner, if he or she chooses, to contest the order within 15 days of receipt of the order notice by requesting in writing a hearing before the president of the Board of Pharmacy.<sup>22</sup>

The following are the general requirements that must be in place in order for a pharmacy operation to be considered for conducting sterile injectable compounding:

- The sterile injectable compounding area:<sup>23</sup>
  - The room and work station shall be clean and the walls, ceilings and floors shall be of special construction in accordance with the requirements described in Title 24, CCR, Sec. 1250
  - The ventilation system shall be in accordance with the requirements described in Title 24, CCR, Sec. 505.12.

- The sterile compounding area and laminar air flow hoods shall be certified annually by a qualified technician. Certification records must be maintained for at least 3 years.
- The items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
- A sink with hot and cold running water shall be maintained in addition to a refrigerator and/or freezer of sufficient capacity shall be in the room to accommodate for the storage of materials requiring refrigeration.
- There shall be facility and equipment standards:<sup>24</sup>
  - No sterile injectable product shall be prepared if the compounding environment fails to meet the criteria stated in the pharmacy's written policies and procedures.
  - Access to the designated sterile compounding area is to be limited to only those individuals who are properly attired.
  - All equipment in the sterile compounding area must be made of material that can be easily cleaned and disinfected.
  - All surfaces in the sterile compounding area such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.
- There shall be policies and procedures regarding the following that shall include:<sup>25</sup>
  - Compounding, filling, and labeling of sterile compounds.
  - Labeling of the sterile injectable product based on the intended route of administration and rate of administration.

- The type and use of equipment and supplies.
  - The training of staff in the preparation of sterile injectable products.
  - Procedures for handling cytotoxic agents.
  - A quality assurance program.
  - Record keeping requirements.
  - The ingredients and the compounding process for each preparation requiring a review by a pharmacist.
  - The competency evaluations employed.
  - Methods of storing and handling products and supplies.
  - Storage and delivery of final products.
  - Process validation.
  - Personal access and movement of materials into and near the controlled area.
  - Use and maintenance of environmental control devices and equipment (e.g., laminar-airflow workstations, biological safety cabinets, etc.)
  - Cleaning schedules for the controlled area and equipment contained within and a detailed infection control policy.
  - Disposal procedures of various equipment and supplies contained within the sterile compounding area.
  - Maintenance of records that describe formulations and work sheets used to serve as documentation.
  - End-product evaluation and testing.
- Labeling requirements for compounded sterile injectable products:<sup>26</sup>
    - Must contain the telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
    - Name and concentrations of ingredients contained in the sterile injectable product.
    - Instructions for storage and handling.
    - All cytotoxic agents shall bear a special label which states, "*Chemotherapy-Dispose of Properly.*"

- **Recordkeeping Requirements:**<sup>27</sup>
  - Pharmacies compounding sterile injectable products for future use shall have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
  - Sterile products compounded from one or more non-sterile ingredients shall maintain the following records for at least 3 years:
    - The training and competency evaluation of employees in sterile product procedures.
    - Refrigerator and freezer temperatures.
    - Certification records of the sterile compounding environment.
    - Cleaning logs for facilities and equipment.
    - Inspection for expired or recalled pharmaceutical products or raw materials.
    - Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
- **Attire:**<sup>28</sup>
  - When preparing cytotoxic agents, gowns and gloves shall be worn.
  - When compounding sterile products:
    - Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the sterile preparation area at all times.
    - Cleanroom garb must be donned and removed outside the designated area.
    - Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
    - Head and facial hair must be kept out of the critical area or be covered.
    - Gloves made of low-shedding materials are required.

- **Training of Staff, Patient, and Caregiver:**<sup>29</sup>
  - Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
  - The pharmacist-in-charge shall be responsible to ensure that all pharmacy personnel engaged in compounding sterile injectable products shall have training and demonstrate competence in the safe handling and compounding of these products, including cytotoxic agents. These training programs and ensuring that competence is maintained shall be ongoing and shall include such areas of continued training and evaluation in:
    - Aseptic technique.
    - Pharmaceutical calculations and terminology.
    - Sterile product compounding documentation.
    - Quality assurance procedures.
    - Aseptic preparation procedures.
    - Proper gowning and gloving technique.
    - General conduct in the controlled area.
    - Cleaning, sanitizing, and maintaining equipment used in the controlled area.
    - Sterilization techniques.
    - Container, equipment, and closure system selection.
- There shall be records of training and demonstrated competence involved in sterile injectable compounding and these records shall be kept for 3 years.<sup>30</sup>
- The evaluation of those involved in sterile injectable preparation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every



12 months. Results of these assessments must be retained for 3 years.<sup>31</sup>

- **Disposal of Waste Material:**<sup>32</sup>
  - There must be written policies and procedures for the disposal of infectious materials and/or cytotoxic materials.
  - The procedures shall include cleanup of spills and shall be in conformance with local health policies.
- **Quality Assurance:**<sup>33</sup>
  - Cleaning and sanitization of the parenteral medication preparation area.
  - Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end-product testing for sterility and pyrogens and shall be quarantined until the end-product testing confirms sterility and acceptable levels of pyrogens.
  - The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperatures.
  - Steps to be taken in the event of a drug recall.
  - Written justification of the chosen expiration dates for compounded sterile injectable products.
  - Each person involved in the preparation of sterile injectable products must successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is required to prepare. If microbial growth is detected in samples taken, the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every 12 months and documented if:

- The quality assurance program yields an unacceptable result.
  - When the compounding process changes.
  - When equipment used in the compounding of sterile injectable drug products is repaired or replaced.
  - When the facility is modified in a manner that affects airflow or traffic patterns.
  - Whenever improper aseptic techniques are observed.
- **Reference Materials:**<sup>34</sup>
    - There shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available in the pharmacy.

***ARE THERE EXCEPTIONS TO THE STERILE  
INJECTABLE COMPOUNDING LAWS WHERE  
SEPARATE LICENSING WOULD NOT BE REQUIRED?***

The major exception to where preparation of a sterile injectable product would not require a separate license by the Board is the following as stated in the statute:<sup>35</sup>

*“The reconstitution of a sterile powder shall not require a ‘special or separate’ license if both of the following are met:*

- (1) The sterile powder was obtained from a manufacturer.*
- (2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection.”*

**MAY NONRESIDENT PHARMACIES TRANSPORT  
STERILE INJECTABLE DRUG PRODUCTS  
INTO CALIFORNIA?**

A nonresident pharmacy (a pharmacy in another state) may only compound injectable sterile drug products for shipment in California if they possess a license from the California State Board of Pharmacy.<sup>36</sup> Once the out-of-state pharmacy is licensed by California to ship compounded sterile injectables, that pharmacy must basically follow the same guidelines discussed previously:<sup>37</sup>

- The license shall be renewed annually and is not transferable.
- The license will only be issued to a pharmacy.
- The license may only be issued to the owner of the nonresident pharmacy license at the location of the pharmacy.
- The issuance or renewal of the license will only occur if the California Board of Pharmacy receives the following:<sup>38</sup>
  - A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the Board.
  - Documentation from the last 12 months that the pharmacy has been in compliance with Board regulations regarding the compounding of injectable sterile drug products.
  - A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.
- A nonresident pharmacy licensed as a hospital, home health agency, or a skilled nursing facility and having current accreditation from the JCAHO, or other private accreditation agencies approved by the California Board of Pharmacy, are exempt from the requirements to obtain a sterile injectable compounding license from the California Board.<sup>39</sup>

***WHAT GUIDELINES SHOULD A PHARMACIST  
CONSIDER TO ENSURE THAT COMPOUNDING  
IS NOT CONSTRUED AS MANUFACTURING?***

While compounding of drug products is recognized under California Pharmacy Law as an acceptable component of pharmacy practice, pharmacists need to be careful that they do not violate Federal Food and Drug Administration laws, as well as California Health and Safety codes that draw distinctions between compounding and manufacturing.<sup>40</sup> In the Summer 1995 edition of the California Board of Pharmacy's publication "*The Script*," the Board outlines some of the instances where pharmacists may be transgressing into highly regulated manufacturing activities, rather than performing normal compounding tasks. These instances include, but are not limited to, the following:<sup>41</sup>

- Where no professional relationship exists among the prescriber, the patient, and the pharmacist who compounds and dispenses the drug product.
- Where the pharmacy compounds products which are exact generic copies of F.D.A. approved, commercially available, drug products.
- Where the pharmacy is receiving and using drug substances without obtaining and retaining evidence of the source of such substances or the method of their preparation.
- Where the pharmacy is compounding drugs in high volume in anticipation of receiving prescriptions, rather than compounding a prescription that is presented by a patient. This ruling has been relaxed somewhat with the introduction of Section 1735.2[b] of the California Code of Regulations
- Where large amounts of compounded drugs are distributed to patients outside of the pharmacy's normal trade area or across state lines.
- Where drugs are being compounded by one pharmacy to be dispensed by another pharmacy. However, Section 4033[b] of the California Business and Professions Codes

does provide for an exception in its statement that, "Manufacturer shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to a patient or patients named on the prescription, provided that neither the components for the drug nor the drug are compounded,... packaged, or otherwise prepared prior to receipt of the prescription."<sup>42</sup>

- Where the pharmacy is compounding drug products not deemed safe and/or effective, and where there is not substantiating scientific literature to support the use of such compounded drug products.

The above list is only a partial representation of where drug compounding activities may cross over into the more strictly regulated area of manufacturing, which requires rigid compliance to both the F.D.A. and California Health and Safety Codes.

### ***WHAT ARE THE REQUIREMENTS ON COMPOUNDING UNAPPROVED DRUGS FOR A PRESCRIBER'S OFFICE USE?***

Generally a compounded substance results in a F.D.A. unapproved drug even though each of the active ingredients incorporated into the compounded product, by themselves, are recognized as F.D.A. approved ingredients. The end-product of mixing the two or more F.D.A. approved ingredients has not gone through the rigors of drug testing in their combined form.

A pharmacist may furnish to a prescriber a reasonable quantity of compounded medication for the prescriber's office use.<sup>43</sup> A "reasonable" quantity shall mean that quantity of the compounded drug that is sufficient for that prescriber's office use consistent with his or her practice.<sup>44</sup>



The amount provided shall bear a proper expiration date which will not exceed 180 days or the expiration date of any individual component of the compounded product, which ever is less.<sup>45</sup> Further, the use of the compounded medication should be consistent with the nature of the prescriber's practice.<sup>46</sup> "Prescriber's office use" shall mean:<sup>47</sup>

- The compounded drug is to be applied or administered in the prescriber's office, or
- If dispensed, not more than a 72 hour supply of the compounded drug is to be given by the prescriber to the patient.

### ***WHAT ARE THE REQUIREMENTS ON COMPOUNDING FOR FUTURE FURNISHING?***

When a pharmacy compounds a drug or drugs in quantities larger than what is required for immediate dispensing, or intended to be used for future dispensing, the pharmacy shall maintain the following records:<sup>48</sup>

- The date of the preparation.
- Active and inactive ingredients to be used.
- Process and/or procedure used to prepare the drug.
- Quality reviews required at each step in preparation of the drug.
- The lot number and expiration date of each of the ingredients. If these are not known, the pharmacy shall record the source and acquisition date of each ingredient.
- Proper labeling requirements.
- Any storage requirements.
- The expiration date of the finished product, which will not exceed 180 days or the shortest expiration date of any of the ingredients, whichever is less. An even shorter date may be used if deemed appropriate by the pharmacist.
- The signature or initials of the pharmacist performing the compounding.
- A master formula for the compounded product.

- The name(s) of the manufacturer(s) of the raw materials.
- The quantity in units of finished products or grams of raw materials.
- The package size and number of units prepared.

***WHAT WAS THE OUTCOME FOR PHARMACY  
REGARDING COMPOUNDING BASED UPON THE U.S.  
SUPREME COURT'S FINDING PERTAINING TO THE  
FDA MODERNIZATION ACT OF 1997?***

The pharmacy compounding provision in the FDA Modernization Act of 1997 (FDAMA) was found to be unconstitutional according to the 9<sup>th</sup> Circuit Court in February, 2001 (see *Western States Medical Center v. Shalala*) and in late April 2002, the lower court's decision was affirmed in part by the U.S. Supreme Court (see *Thompson v. Western States Medical Center*).

The portion of the Act that was found to be unfavorable to pharmacy practice was the section that disallowed a pharmacist to advertise that they could compound specific drug products. The Act did not interfere with a pharmacy advertising that it offered general compounding services, but did not allow a pharmacy or pharmacist to advertise or promote the compounding of a specific drug, drug class, or drug type. As a result of the U.S. Supreme Court's decision, the portion of the act that disallowed advertising by a pharmacy that it provided specific drug compounding services, was viewed as a First Amendment freedom of speech violation.

The following is a segment of the opinion that sheds light on why the majority of the Justices of the U.S. Supreme Court formed their decision to overturn the Act:

*“Forbidding the advertisement of compounded drugs would prevent pharmacists with no interest in mass-producing medications, but who serve patients with special medical needs, from telling the doctors treating*

*those patients about the alternative drugs available through compounding. For example, a pharmacist serving a children's hospital where many patients are unable to swallow pills would be prevented from telling the children's doctors about a new development in compounding that allowed a drug that was previously available only in pill form to be administered in another way. The fact that the FDAMA would prohibit such seemingly useful speech even though doing so does not appear to directly further any asserted government objective confirms that the prohibition is unconstitutional."*<sup>49</sup>

# REFERENCES TO CHAPTER 11

1. *Title 16, CA code of Regs, Secs. 1735-1735.8*
2. *Ibid. at Sec. 1735*
3. *Ibid. at Sec. 1735.2[a]*
4. *Ibid. at Sec. 1735.2[b]*
5. *Ibid. at Sec. 1735.2[d][e]*
6. *Ibid. at Sec. 1735.2[h]*
7. *Ibid. at Sec. 1735.2[j]*
8. *Ibid. at Sec. 1735.2[j]*
9. *Ibid. at Sec. 1735.3[a][b][c][d]*
10. *Ibid. at Sec. 1735.4*
11. *Calif. Bus. & Prof. Code, Secs. 4029, 4128, 4128.2, 4128.3, 4128.4, & 4128.5*
12. *Title 16, Calif. Code of Regs., Sec. 1735.5*
13. *Ibid. at Sec. 1735.6*
14. *Ibid. at Sec. 1735.7*
15. *Ibid. at Sec. 1735.8*
16. *Calif. Bus. & Prof. Code, Sec. 4127.1[a]*
17. *Ibid. at Sec. 4127.1[a][b]*
18. *Ibid. at Sec. 4127.1[c]*
19. *Ibid. at Sec. 4127.1[d]*
20. *Ibid. at Sec. 4127.3[a]*
21. *Ibid. at Sec. 4127.3[a]*
22. *Ibid. at Sec. 4127.3[c]*
23. *Title 16, Calif. Code of Regs., Sec. 1751*
24. *Ibid. at Sec. 1751.4*
25. *Ibid. at Sec. 1751.3*
26. *Ibid. at Sec. 1751.2*
27. *Ibid. at Sec. 1751.1*
28. *Ibid. at Sec. 1751.5*
29. *Ibid. at Sec. 1751.6[a][b][e]*
30. *Ibid. at Sec. 1751.6[c]*
31. *Ibid. at Sec. 1751.6[e][2]*
32. *Ibid. at Sec. 1751.3[c][e][3[H]]*
33. *Ibid. at Sec. 1751.7*
34. *Ibid. at Sec. 1751.8*
35. *Calif. Bus. & Prof. Code, Sec. 4127.1[e]*
36. *Ibid. at Sec. 4127.2[a]*

37. *Ibid.* at Sec. 4127.2[b]
38. *Ibid.* at Sec. 4127.2[b][1][2]
39. *Ibid.* at Sec. 4127.2[c]
40. *Ibid.* at Sec. 4033[a]
41. Summer 1995 Edition of “*The Script*,” a publication of the Calif. State Board of Pharmacy.
42. Calif. Bus. & Prof. Code, Sec. 4033[b]
43. Title 16, Calif. Code of Regs., Sec. 1735.2[c]
44. Calif. Bus. & Prof. Code, Sec. 4052
45. Title 16, Calif. Code of Regs., Sec. 1735.2[h]
46. *Ibid.* at Sec. 1735.2[c][2]
47. *Ibid.* at Sec. 1735.2[c][1]
48. *Ibid.* at Sec. 1735.2[b][c][d][e][f][g][h][i]
49. *Thompson v. Western States Medical Center* (2002 DJDAR 4627 [April 29,2002]).



## CHAPTER 12

### CLASSIFICATIONS OF SCHEDULED CONTROLLED SUBSTANCES

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## **WHAT DRUGS CONSTITUTE THE SCHEDULE II CONTROLLED SUBSTANCES?**

When drugs such as codeine and camphorated tincture of opium are added to a non-narcotic medicinal agent, they lose their Schedule II status or the need for a prescriber to write it as a Schedule II prescription, and the drug order may become a Schedule III, IV, or V controlled substance classification. Your California law book lists a number of narcotics in this class which either are not used very much or have been discontinued by the manufacturer. Therefore, the list below presents only those Schedule II drugs that are presently used.<sup>1</sup>

TABLE 1

**NARCOTIC SUBSTANCES (C-II)**

<u>Generic Name</u>	<u>Common Trade Name</u>
Alfentanil .....	Alfenta
Alphaprodine.....	Alphaprodine
Codeine .....	Codeine Sulfate/Phosphate
Dihydrocodeine.....	Drocode, Paracodin, Dicogesic
Fentanyl .....	Sublimaze or Fentanyl
Hydromorphone .....	Dilaudid
Levoalphacetylmethadol.....	L.A.A.M. ( <i>used in treatment of narcotic drug addiction</i> )
Levorphanol .....	Levo-Dromoran
Meperidine .....	Demerol or Meperidine
Methadone.....	Methadone
Morphine .....	Morphine Sulfate
Opium .....	Tinct. Of Opium or Camphorated Tinct. of Opium or Paregoric ( <i>Sched. II in Ca. &amp; Sched. III Federally</i> )
Oxycodone .....	Percodan/Percocet
Oxymorphone .....	Numorphan, Opana ER
Sufentanil .....	Sufenta

TABLE 2

## ANTIEMETIC SUBSTANCES (C-II)

<u>Generic Drug</u>	<u>Common Trade Name</u>
Nabilone .....	Cesamet

TABLE 3

## STIMULANT SUBSTANCES (C-III)

<u>Generic Name</u>	<u>Common Trade Name</u>
Amphetamine .....	Amphetamine Sulfate
Cocaine .....	Cocaine HCl
Dextroamphetamine .....	Dexadrine
Dexmethylphenidate.....	Focalin
Khat (from Catha Edulis plant).....	Khat or African Tea
Methamphetamine .....	Desoxyn, Methadrine
Methylphenidate .....	Ritalin
Phenmetrazine HCl .....	Preludin

TABLE 4

## DEPRESSANT SUBSTANCES (C-III)

<u>Generic Name</u>	<u>Common Trade Name</u>
Amobarbital .....	Amytal (does not include suppositories, which are Schedule III)
Glutethimide .....	Doriden (Sched. II in Ca. & Sched. III federally)
Pentobarbital .....	Nembutal (does not include suppositories, which are Schedule III)
Secobarbital .....	Seconal (does not include suppositories, which are Schedule III)

### WHAT DRUGS CONSTITUTE THE SCHEDULE III CONTROLLED SUBSTANCES<sup>2</sup>

TABLE 5

## ANTIEMETIC SUBSTANCES (C-III)

<u>Generic Drug</u>	<u>Common Trade Name</u>
Dronabinol .....	Marinol

**TABLE 6**  
**NARCOTIC SUBSTANCES (C-III)**

- A. Not more than 1.8 gms of codeine or hydrocodeine per 100 ml., or not more than 90 mg per dosage unit with one or more non-narcotic ingredients.
- B. Not more than 300 mgs of dihydrocodeinone per 100 ml., or not more than 15 mgs per dosage unit with one or more non-narcotic ingredients.
- C. Not more than 500 mg of opium per 100cc or per 100 gms, with one or more non-narcotic ingredients.
- D. Not more than 50 mg of morphine per 100cc or 100 gms, with one or more non-narcotic ingredients.
- E. Buprenorphine (also buprenorphine w/ naloxone) .... Subutex and Subuxone

**TABLE 7**  
**STIMULANT SUBSTANCES (C-III)**

- A. Any stimulant substance listed under Schedule II in a mixture or which contains a lesser quantity of the stimulant with one or more non-stimulant ingredients.
- B. Also,

<u>Generic Name</u>	<u>Common Trade Name</u>
Benzphetamine .....	Didrex
Mazindol .....	Sanorex or Mazanor (Sched. III in Calif. & Sched. IV federally)
Phendimetrazine .....	Bontril, Plegine, & Prelu-2

**TABLE 8**  
**DEPRESSANT SUBSTANCES (C-III)**

- A. Any mixture containing amobarbital, secobarbital, or pentobarbital plus a medicinal ingredient which is not listed in any Schedule.
- B. Any suppository dosage form containing any of the following: amobarbital, secobarbital, or pentobarbital.
- C. Also,

<u>Generic Name</u>	<u>Common Trade Name</u>
Aprobarbital.....	Alurate
Butabarbital .....	Butisol
Gamma Hydroxybutyric Acid (GHB)*	
Ketamine .....	Ketalar
Metharbital .....	Gemonil
Methypylon .....	Noludar
Talbutal .....	Lotusate
Thiamyltal .....	Surital
Thiopental .....	Pentothal

\* GHB, and its salts, isomers and salts of isomers contained in a drug product for which an application has been approved by the FDA shall be in Schedule III. If not approved, GHB shall be designated as a Schedule I controlled substance.

**TABLE 9**  
**ANABOLIC STEROIDS (C-III)**

There have been a whole host of anabolic steroid products that have been added to the Schedule III Controlled Substances under the Anabolic Steroid Control Act of 2004. Many of these chemical entities were available over-the-counter and on the street, and now because of the evidence of steroid-like properties and the related inherent medical problems associated with this class of chemical substances they have been placed under a Controlled Substances designation.

<u>Generic Name</u>	<u>Common Trade Name</u>
Androisoxazole	
Androstenediol and Derivatives	
Androstenedione and Derivatives	
Bolandiol	
Bolasterone	
Boldenone	
Chlormethandienone	
Chorionic Gonadotropin (HCG) .....	A.P.L., Pregnyl
Clostebol	
Dihydromesterone	
Ethylestrenol	
Fluoxymesterone .....	Halotestin
Formyldienolone	
4-Hydroxy-19-nortestosterone	
Mestanolone	
Methandriol	
Methandrostenolone	
Methenolone	
Methyltestosterone .....	Oreton, Android, Testred
Methyltrienolone	
Nandrolone .....	Durabolin
Norbolethone	
Norethandrolone	
Normethandrone	
Oxandrolone .....	Oxandrin
Oxymesterone	
Oxymetholone .....	Anadrol
Quinbolone	
Stanolone	
Stanozolol .....	Winstrol
Stenbolone	
Testosterone .....	Delatestryl
Trenbolone	



# WHAT DRUGS CONSTITUTE THE SCHEDULE IV CONTROLLED SUBSTANCES<sup>3</sup>

TABLE 10

## NARCOTIC-ANALGESIC SUBSTANCES (C-IV)

<u>Generic Name</u>	<u>Common Trade Name</u>
Difenoxin 1 mg + Atropine .....	Motofen
Dextropropoxyphene (+ any non-narcotic analgesic) .....	Darvon
Pentazocine .....	Talwin

TABLE 11

## STIMULANT SUBSTANCES (C-IV)

<u>Generic Name</u>	<u>Common Trade Name</u>
Diethylpropion .....	Tenuate, Tepanil
Fenfluramine .....	Pondimin
Phentermine .....	Fastin, Ionamin
Pemoline .....	Cylert

TABLE 12

## DEPRESSANT &amp; ANTIANXIETY SUBSTANCES (C-IV)

<u>Generic Name</u>	<u>Common Trade Name</u>
Alprazolam .....	Xanax
Barbital.....	Veronal
Carisoprodol.....	Soma
Chloral Betaine.....	Beta-Chlor
Chloral Hydrate .....	Noctec
Clobazam.....	Mystan ( <i>anticonvulsant</i> )
Chlordiazepoxide .....	Librium
Clonazepam .....	Klonopin ( <i>Primary use as an anticonvulsant</i> )
Clorazepate .....	Tranxene
Diazepam .....	Valium
Dichloralphenzone.....	Midrin
Estazolam.....	ProSom, Domnamid, Eurodin, Nuctalon
Eszopiclone.....	Lunesta
Ethchlorvynol .....	Placidyl
Ethinamate .....	Valmid
Flunitrazepam.....	Rohypnol, Narcozep, Darkene, Roipnol
Flurazepam .....	Dalmane
Halazepam .....	Paxipam
Lorazepam .....	Ativan
Mebutamate.....	Capla
Mephobarbital .....	Mebaral
Meprobamate .....	Equanil, Miltown
Methohexital .....	Brevital
Midazolam .....	Versed
Nitrazepam.....	Mogadon

TABLE 12 Continued

DEPRESSANT & ANTIANXIETY SUBSTANCES (C-IV)

<u>Generic Name</u>	<u>Common Trade Name</u>
Nordiazepam.....	Nordazepam, Demadar, Madar
Oxazepam .....	Serax
Oxazolam.....	Serenal, Converal
Paraldehyde .....	Paral
Petrichloral.....	Periclor
Phenobarbital .....	Luminal
Prazepam .....	Centrax
Quazepam .....	Doral
Temazepam .....	Restoril
Triazolam .....	Halcion
Zaleplon.....	Sonata
Zopiclone.....	Lunesta
Zolpidem.....	Ambien, Ivadal, Stilnoct, Stilnox

WHAT DRUGS CONSTITUTE THE SCHEDULE V  
CONTROLLED SUBSTANCES?<sup>4</sup>

TABLE 13

NARCOTIC SUBSTANCES (C-V)

- A. Mixture of not more than 200 mg of codeine per 100cc or per 100 gms added to a non-scheduled active drug.
- B. Mixture of not more than 100 mg of dihydrocodeine per 100 cc or per 100 gms added to a non-scheduled active drug.
- C. Mixture of not more than 100 mg of opium per 100cc or per 100 gms added to a non-scheduled active drug.
- D. Also,

<u>Generic Drug</u>	<u>Common Trade Name</u>
Difenoxin 0.5 mg + Atorpine .....	Motofen
Diphenoxylate 2.5 mg + Atropine .....	Lomotil
Pregabalin.....	Lyrica <sup>5</sup>

**REFERENCES TO CHAPTER 12**

1. Calif. Health & Safety Codes, Secs. 11055 & 11169
2. *Ibid.* at Sec. 11056
3. *Ibid.* at Sec. 11057
4. *Ibid.* at Sec. 11058
5. *Pregabalin (Lyrica®) by Pfizer, although in the same classification as Gabapentin (Neurontin®) used in the management of peripheral neuropathy and postherpetic neuralgia has been categorized as a Schedule V Controlled Substance while Gabapentin still remains as a non-controlled substance. Pregabalin appears to cause euphoria in a small percentage of patients when used in higher doses that evidently caused concern to categorize the drug as a Schedule V Controlled Substance. Gabapentin because of its long history on the market still remains a non-scheduled controlled substance.*

## CHAPTER 13

### ***SPECIAL CONSIDERATIONS IN DEALING WITH SCHEDULE II CONTROLLED SUBSTANCES***

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**IS THE CONTROLLED SUBSTANCE UTILIZATION  
REVIEW AND EVALUATION SYSTEM (CURES)  
STILL IN EFFECT?**

The Controlled Substance Utilization Review and Evaluation System or the CURES Program is still in effect. At present all Schedule II, III, and IV controlled substance prescriptions filled at a pharmacy must be transmitted by the Internet on a weekly basis or sooner to the federal CURES data base that allows the DEA and Department of Justice, and other government agencies to more closely monitor the prescribing of controlled substances.<sup>1</sup>

According to the Calif. Health and Safety Codes the reporting requirement for Schedule IV controlled substances to CURES shall not apply when the amount dispensed pursuant to a prescription is a 48 hour supply or less.<sup>2</sup> And, if the amount dispensed for a Schedule II or III controlled substance is for a period of 48 hours or less this will require only a "monthly" (statute says "monthly" not "weekly") reporting to CURES.<sup>3</sup>

By converting to an on-line system where all information regarding the filling of Schedule II, III and IV controlled substances are sent to a central receiving bank the following is accomplished:

- 1) It will eliminate the need for the State to generate the old *Triplicate* forms, and such prescriptions can easily be written in the hand of the prescriber on special single copy security prescription forms to be ordered by the prescribers from a security printer approved by the Department of Justice.<sup>4</sup> (In the past the *Triplicate* prescription form was a method used by California prescribers for ordering prescriptions for Schedule II controlled substances only prior to 2005. At present the single security prescription form is used by the prescriber for ordering all Schedule controlled substances for patients. The older *Triplicate* forms are now obsolete and have not been used in the filling of

Schedule II controlled substances for the last 7 to 8 years and these prescription forms are no longer valid for writing prescriptions for Schedule II controlled substances);

- 2) It will entail less paperwork for the pharmacist where *Triplicate* forms in the past had to be submitted at the end of the month to the Department of Justice. Copies of the new security form prescriptions do not have to be submitted to the Department of Justice at the end of the month;
- 3) It will allow for the federal government or State government agencies to have quick access to those prescribers, pharmacies, and possibly patients who may be potential abusers of drugs in the Schedule II, III, and IV class of controlled substances; and
- 4) It will allow both pharmacists and the DEA to quickly identify, via computer transmission, any potential problem with a Schedule II, III, or IV prescription order intended to be filled.

Concerning point 4) above, the pharmacist is given the opportunity to request in writing from the Department of Justice the history of a patient's usage of Schedule II, III, or IV controlled substances and receive such information if:<sup>5</sup>

- The pharmacist provides a notarized application to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient maintained within the CURES data base. The submitted application may be denied for a variety of reasons (false information on the application, a suspended or revoked DEA registration, having a criminal record, or attempting to acquire information via the CURES Program for reasons other than caring for a patient at the pharmacy, etc.).
- Once the pharmacist becomes a recognized subscriber by the Department of Justice, the pharmacist may only

inquire about the controlled substance utilization of patient's that are serviced by the pharmacy. A pharmacist who is a recognized subscriber cannot inquire or receive information from the CURES data base on prescribers, other pharmacists, nor patients or individuals who are not clientele that fill prescriptions at the subscribing pharmacist's pharmacy.

- The information is in the data bank of the CURES Program.
- The patient receiving Schedule II, III, or IV controlled substances is under the care of the pharmacist/pharmacy requesting the information.
- There is reasonable suspicion of inappropriate or illegal use of a Schedule II, III, or IV controlled substance.
- The pharmacist submits a request in writing regarding a patient's controlled substance prescription history that follows the guidelines established by the Department of Justice.
- The pharmacist receiving the history of controlled substances dispensed to an individual patient based on information contained in the CURES data base maintains such information as confidential in accordance with HIPAA regulations and the provisions of the California Confidentiality of Medical Information Act.<sup>6</sup>

Under no circumstance can a pharmacist contact the Department of Justice to receive controlled substance use by a patient unless the pharmacist and pharmacy have received approval from the DOJ and are certified to receive such information.

***WHAT PROCEDURES MUST BE FOLLOWED  
REGARDING THE ELECTRONIC MONITORING OF  
SCHEDULE II, III, AND IV PRESCRIPTIONS UNDER  
THE "CURES" PROGRAM?***

Each pharmacy participating in the CURES Program shall send the following information regarding

Schedule II, III, or IV controlled substances dispensed pursuant to a prescription to the State Department of Justice on a weekly basis by means of a computer on-line transmission in a format specified by the Department of Justice:<sup>7</sup>

- Name, address, and telephone number of the patient.
- Gender and date of birth of the patient.
- Prescriber's category and license number.
- DEA registration number of the prescriber.
- The prescription number used by the pharmacy.
- The pharmacy's license number and federal controlled substance registration number.
- The National Drug Code (NDC) number and the quantity of the Schedule II, III or IV drugs dispensed.
- The ICD-9 (diagnosis code) if available or known.
- The date the prescription was issued to the patient.
- The number of refills ordered.
- Whether the drug was dispensed as a refill or as a first time prescription request.
- Date of origin of the prescription.
- The State medical license number of any prescriber using the DEA number of a government exempt facility.

An on-line number is available to forward the above information for each Schedule II, III, or IV drug dispensed pursuant to a prescription. On-line transmission of this information shall be made every week in the format specified by the Department of Justice as noted above. As a result of sending this information in on-line weekly by the pharmacy no longer requires to also report or send this information regarding Schedule II controlled substances to the California Department of Justice at the end of each month as a pharmacy had to do when the old hard-copy *Triplicate* prescription forms were utilized prior to 2005.



***WHAT REQUIREMENTS EXIST FOR THE  
SPECIAL SECURITY PRESCRIPTION FORMS  
NEEDED BY THE PRESCRIBER TO ORDER  
CONTROLLED SUBSTANCES FOR A PATIENT?***

All prescription forms as previously stated for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice.<sup>8</sup> The Department of Justice shall maintain a list of approved security printers and the department shall make this information available to prescribers and other appropriate government agencies, including the Board of Pharmacy.<sup>9</sup> The Department of Justice may revoke its approval of a security printer for violation of any of the standards associated with the ensuring of the security of these prescription forms.<sup>10</sup>

The security prescription forms for controlled substances shall have the following features:<sup>11</sup>

- A latent, repetitive “void” pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word “void” shall appear in a pattern across the entire front of the prescription.
- A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words “California Security Prescription.”
- A chemical void protection that prevents alteration by chemical washing.
- A feature printed in thermo-chromic ink.
- An area of opaque writing so that the writing disappears if the prescription is lightened.
- A description of the security features included on each prescription form.
- Six quantity check-off boxes shall be printed on the form and the following quantities shall appear: *1-24, 25-49, 50-74, 75-100, 101-150, 150 and over.*
- In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity

boxes when the drug is not in tablet or capsule form.

- Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered for Schedule III, IV, or V controlled substances.
- The prescription blanks shall contain a statement printed on the bottom of the prescription blank in order to differentiate the security prescription as a single controlled substance entry prescription or as a multiple entry prescription form (two different prescription forms must be used since multiple controlled substance drugs cannot be entered on a security prescription if it is intended for only one controlled substance drug entry).
  - *Security prescription intended for only one controlled substance drug entry:*
    - Printed, usually at the bottom of the prescription will be the following - *“This prescription is void if more than one controlled substance prescription is written per blank.”*
    - The drug, strength, quantity (there will be a column on the left of the prescription that will require that the prescriber checks off the approximate quantity ordered – e.g. 1-24, 25-49, 50-74, etc.), and directions. This information can be either written in or typed in (this includes all the Scheduled controlled substances); however, the prescriber must both sign and date the prescription.
  - *Security prescription intended for multiple controlled substance drug entries:*
    - Printed, usually at the bottom of the prescription will be the following - *“This prescription is void if the number of drugs prescribed is not noted...(the number of controlled substance drugs ordered must be noted after this statement)”*.
    - This multiple prescription form will usually be divided by lines possible for between 3 and 5 controlled substance entries.

- A column to the left for each line item will have a series of quantity amounts to be checked off (e.g. 1-24, 25-49, 50-74, 75-100, etc.). Also in this column for each line will be a place to indicate the number of refills (only for Schedule III, IV, and V controlled substances) along with notice whether or not the prescriber wishes to have substitution (along with a space to place the prescriber's initial if he or she does not wish to have substitution).
- On the security multi-prescription form, entries can include Schedule II controlled substances along with Schedule III, IV, and V controlled substances.
- Again, the drug, strength, quantity, and directions can either be handwritten or typed in as long as the prescriber signs and dates the prescription.
- The prescriber may indicate the dispensing of the multiple controlled substances at different dates as long as the date when the prescription was written is the true date it was written. In other words, if there are three controlled substances and the date of writing the prescription is January 1, 20xy, that date must be shown, and be the true date the prescription was written (antedating or postdating a controlled substance prescription is illegal). However, there can be different dates requested for the dispensing of the 3 example drugs:
  - Example CS Drug A – *“Dispense January 1, 20xy.”*
  - Example CS Drug B - *“Dispense February 1, 20xy.”*
  - Example CS Drug C – *“Dispense March 1, 20xy.”*

This above arrangement appears not to be in any violation of either the federal or state laws,

however, there may be some challenges forthcoming possibly by the DEA. So far, this arrangement is not being challenged as a violation of the refilling rule applied to Schedule II controlled substances.

- The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.
- Security prescription forms for prescribers in a health-care facility where there are less than 25 prescribers, may utilize a security form with each prescriber's name listed, along with their category of license, license number, DEA registration number and a check-off box with a signature entered below with the date the prescription is written in the prescriber's handwriting. Also, the name, address, category of licensure, and license number of the licensed healthcare facility must be on the facility's security form. The facility must keep records of the number of controlled substance security prescriptions. These records must be kept for 3 years.<sup>12</sup> For healthcare facilities (such as clinics) having 25 or more prescribers, the rules are different as discussed below in the next section.<sup>13</sup>
- Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

To repeat, these security prescription forms are to be the exclusive form that the prescriber must use when he or she issues a written order for a controlled substance for an ambulatory patient whether it be a Schedule II, III, IV, or V controlled substance. There is however an exception when a prescription for a Schedule II, III, IV, or V controlled substance is ordered for a terminally ill patient. This exception is discussed below in this Chapter under the heading, *"May A Schedule II Controlled Substance Prescription For A Terminally Ill Patient Be Written On A*

*Regular (Non-Security) Prescription Form (The “11159.2 Exemption Rule)?”*

**WHAT RECENT MODIFICATIONS HAVE BEEN MADE IN THE SECURITY PRESCRIPTION FORMS USED IN THE ORDERING OF SCHEDULED CONTROLLED SUBSTANCES?**

The following modifications have been approved by amendment to the statute dealing with the security prescription forms used for ordering scheduled controlled substances:<sup>14</sup>

- The identification number assigned to each approved security printer by the Department of Justice that provides the security forms to practitioners must be preprinted on each prescription form.
- In that a security prescription form can be used by more than one prescriber, a check box must be located next to the name of each prescriber that is printed on the prescription. The prescriber writing the prescription must sign his or her name and check the box by his or her name.
- A prescriber designated by a licensed health care facility or a clinic that has 25 or more physicians may order the security prescription forms for use by prescribers when treating patients in that facility without the requirement of the actual prescriber's preprinted name, license and federal registration numbers. Instead, that prescriber's information may be handwritten, typed, or computer-generated on the security prescription form.
- Refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill.<sup>15</sup>



**HOW MUST THE PRESCRIBER PREPARE A  
PRESCRIPTION FOR A SCHEDULE II  
CONTROLLED SUBSTANCE?**

For each *security form* prescription that is prepared for a patient for a Schedule II drug, the following either must or may occur:<sup>16</sup>

- The prescription for a Schedule II controlled substance must be prepared on a special security prescription form.
- The prescriber must sign his or her name and also place the date issued in ink. These two items must be in the handwriting of the prescriber.
- The remainder of information (patient's name, address, drug name, strength, quantity, directions, DEA number, prescriber's address, etc.) placed on the security prescription may be either typewritten or in the handwriting of the prescriber or his or her employee.

A prescription for a Schedule II controlled substance may be written on a regular prescription blank (not a security prescription blank) when the controlled substance is written for a patient who is terminally ill.<sup>17</sup> All of the information on the regular prescription must be the same as it is for the writing of a Schedule II controlled substance on a special security prescription blank. Again, the name and date must be in the handwriting of the prescriber. The other information on the prescription can be typed or in the handwriting of one of the prescriber's employees. In addition, the prescription must have written or printed on it "*11159.2 Exemption*" that indicates that the prescription is for a terminally ill patient.

The pharmacist may still fill the prescription if there is a technical error whereby the prescriber has not placed information such as "*11159.2 exemption*" indicating the patient is terminally ill, as long as the pharmacist has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for

the clarification to be placed on the prescription within 72 hours.<sup>18</sup>

For further discussion on the prescription requirements for a terminally patient who is being prescribed a Schedule II controlled substance under the “11159.2 Exemption” rule, please refer to the topic heading within this Chapter entitled, “*May A Schedule II Controlled Substance Prescription For A Terminally Ill Patient Be Written On A Regular (Non-Security) Prescription Form (The “11159.2 Rule”)?*”

### ***WHAT IF THE PRESCRIBER MAKES AN ERROR OR FORGETS TO WRITE-IN SOME OF THE REQUIRED INFORMATION ON THE SECURITY PRESCRIPTION?***

If an error or an omission should be noted on a Scheduled II controlled substance prescription prior to January 1, 2005 the pharmacist could fill the prescription if it was an error and provide it to the patient and then contact the prescriber to have him or her acknowledge the error along with the correction by providing a second signature to be received by the pharmacy within seven (7) days. If the problem involved an omission, the pharmacist would have to have the prescription returned to the prescriber for entry of the omitted information.<sup>19</sup>

As a result of the exclusive use of the security form for all scheduled controlled substances, the procedure has now been standardized where the same rule applies to Schedule II controlled substances as it does for Schedule III, IV, and V controlled substances. If there is an error in or omission of information on the security prescription for a Schedule II controlled substance, the pharmacist need only contact the prescriber, discuss with the prescriber the nature of the error or omission, receive clarification of what was actually intended or needed to be added, and the pharmacist incorporate the correct or omitted information onto the security prescription along with documentation that the prescriber was contacted to rectify the error or omission.<sup>20</sup>

While this seems to be the interpretation of the statutes involved, this point of dealing with Schedule II errors or omissions should be better spelled-out in either the statutes or regulations. There is an exception to the pharmacist entering corrections or omissions on the prescription after prescriber verification, and that is where the prescriber did not sign his or name or place the date in his or her own handwriting in ink onto the prescription, the prescription for the Schedule II controlled substance would have to be returned for the handwritten entry of the prescriber's name and date.<sup>21</sup>

***HOW LONG MAY A SECURITY PRESCRIPTION FOR A SCHEDULE II CONTROLLED SUBSTANCE BE HELD BY THE PATIENT BEFORE FILLING?***

A security prescription for a Schedule II controlled substance can be filled up to 6 months from the date it is written.<sup>22</sup>

For example, if the prescriber writes the Schedule II prescription for a patient on January 1<sup>st</sup>, that prescription must be filled no later than June 30<sup>th</sup> of the same year.

There is, however, an exception to the above rule of six months if the prescription is going to be partially filled for an inpatient in a skilled nursing facility:<sup>23</sup>

- The patient must be terminally ill. "Terminally ill" according to state law, means a patient who has a documented diagnosis of an illness or disease that will result in death.
- The Schedule II prescription must be tendered for filling or at least partially filled within 60 days following the date of issue.
- And no portion of the prescription is to be dispensed more than 60 days from the date of issuance.
- Incremental portions of the Schedule II controlled substance may be given multiple times up to the amount written for on the prescription.

***HOW ARE SCHEDULE II CONTROLLED SUBSTANCE PRESCRIPTIONS TO BE FILED IN THE PHARMACY?***

All filled Schedule II prescriptions are to be kept in a filing arrangement that is separate from the Schedule III, IV, and V prescriptions, as well as the nonscheduled drug prescriptions.<sup>24</sup> What if the Schedule II prescription is on a security prescription blank that allows for multiple Schedule controlled substances drug entries of which there are Schedule III, IV, or V, controlled substance drugs ordered as well? Under this circumstance it is suggested that a photocopy of the prescription be made, and one copy be placed in the exclusive Schedule II controlled substance file, and the other copy be placed in the regular files (considering that there may be refills on the other Schedule controlled substance drugs requested), and placing a one inch red "C" in the lower right hand corner if this second copy is placed with the nonscheduled drug files.<sup>25</sup>

(See Chapter 14 under the topic, "*How are Schedule II, III, IV, and V Controlled Substances to be Filed in the Pharmacy After Being Filled?*" for more details about the filing arrangement for Scheduled controlled substance prescriptions in the pharmacy.)

***MAY A PRESCRIBER ORDER A SCHEDULE II CONTROLLED SUBSTANCE FOR A PATIENT OVER THE PHONE IF IT IS FOR AN EMERGENCY CIRCUMSTANCE?***

A prescriber may order a Schedule II controlled substance for a patient without the immediate issuance of a formal and properly executed security prescription if the medication is to be provided during an emergency situation, and is subject to the following requirements:<sup>26</sup>

- It is an emergency where failure to issue a prescription may result in loss of life or intense suffering.

- The order contains all the necessary information.
- Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.
- The prescriber provides a written prescription on a security form for the controlled substance by the seventh day following the transmission of the order to the pharmacy by the prescriber.
- If the prescriber fails to provide the security form prescription within the seven days required, the pharmacy shall notify the Bureau of Narcotic Enforcement in writing within 144 days (six days) of the prescriber's failure to do what is required above. (Also see discussion directly below under next subject heading.)

In the case of a verbal or phone-in emergency order by a prescriber for a Schedule II drug, the pharmacist must write-up the order on a regular prescription that will be destroyed once the pharmacist receives the security prescription for the Schedule II drug (unless the security form prescription is not sent by the prescriber within the 7 days). On this verbal or telephoned-in emergency order prepared prescription by the pharmacist, it might be a good idea to write the words, "*Authorization For Emergency Dispensing*," or words to that effect along with the date the order was requested by the prescriber in order to distinguish this temporary prescription from the more permanent security prescription that will be forwarded by the prescriber.



***WHAT IF THE PRESCRIBER DOES NOT SEND THE  
PHARMACY THE NECESSARY SECURITY  
PRESCRIPTION FOR THE SCHEDULE II WITHIN 7 DAYS  
AFTER AN EMERGENCY REQUEST?***

As previously noted above if for some reason the prescriber does not send or refuses to send a properly executed security prescription to the pharmacy within 7 days after orally requesting a Schedule II drug for a patient with an emergency need, then the pharmacist has an additional 144 hours (6 days) to notify the Bureau of Narcotic Enforcement in writing of the situation.<sup>27</sup>

Upon notifying the Bureau of Narcotic Enforcement, a written record should probably be kept for 3 years that contains the following information:

- The name of the prescriber.
- The name, strength, and quantity of the Schedule II drug dispensed.
- The circumstances under which the emergency prescription was filled.
- The date and method of notification of the Bureau of Narcotic Enforcement
- The name or names of any Bureau of Narcotic Enforcement agents to whom oral notice was furnished.

***MAY A SCHEDULE II CONTROLLED  
SUBSTANCE PRESCRIPTION FOR A  
TERMINALLY ILL PATIENT BE WRITTEN ON A  
REGULAR (NON-SECURITY) PRESCRIPTION FORM  
(THE "11159.2 EXEMPTION" RULE)?***

Beginning January 1, 1999, the State legislature passed a law exempting the writing of the then *Triplicate* prescriptions for Schedule II controlled substances for patients with a terminal illness. With the advent of the security prescription, this same rule applies and does not

require the new security prescription when a Schedule II controlled substance is written for a terminally ill patient. A regular prescription blank may be used by the prescriber and accepted by the pharmacy to order the Schedule II drug for the terminally ill patient if the following statement is either written or typed-in across the prescription, "*11159.2 Exemption*."<sup>28</sup> The exact statement or certification "*11159.2 Exemption*" must be either written or type-set on the regular prescription to be acceptable for filling by the pharmacy. If such a statement or certification does not exist on the prescription or is stated different (e.g. "*1159.3 Terminally Ill Patient*") the pharmacist may still fill the prescription provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.<sup>29</sup> This requirement of returning the prescription to the prescriber within 72 hours, may subsequently change to be consistent with the law that allows the pharmacist to simply contact the prescriber to confirm the correct change, and simply make note of it. Unfortunately Section 11159.2[b] of the Calif. Health and Safety Codes has not yet been modified to incorporate this change.

This form of Schedule II prescription written for a terminally ill patient may be provided in increments based upon the need and condition of the patient.<sup>30</sup> Therefore, as an example, if the prescription is for 100 tablets of a Schedule II drug, to be taken one tablet every 4 hours, and if it is uncertain how long the patient may survive on the basis of their terminal disease, the Schedule II drug can be furnished in increments to cover a few days at a time with the possibility that the patient may expire within a given period of time because of their terminal disease. The purpose of this arrangement appears to address the concern of not allowing full prescriptions for terminally ill patients to be accumulated and stock-piled in places like skilled nursing facilities or hospice care facilities.

There are several other requirements that must be followed for this special arrangement of partial filling for terminally ill patients:<sup>31</sup>

- The patient must fit the criteria of being terminally ill:
  - It has been determined that the patient is suffering from an illness that is incurable and irreversible.
  - The patient's illness will, if the illness takes its normal course, bring about the death of the patient within one year.
  - The patient's treatment with the Schedule II drug is for the control of severe-rated pain, symptom management, or both, rather than for cure of the illness.
- A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.
- The prescription can only be filled up to a 60 day period from the date it is written, whether or not all the medication has been dispensed at the end of that 60 day period.
- No portion of the prescription is to be dispensed more than 60 days from the date of issuance of the prescription.
- If the pharmacist is unable to supply the full quantity ordered by the prescriber of the Schedule II drug, the pharmacist shall make a notation of the quantity supplied on the face of the prescription. The remaining portion may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not

supply the drug after a 72 hour period has expired without a new prescription.

The intent of this legislation appears to be an attempt to have prescribers provide better pain management for those patients in extensive pain who may have cancer or are otherwise terminally ill. Prescribers will hopefully feel more able to aggressively pursue pain management in these difficult cases without being so concerned that the government will suspect them of over-prescribing controlled substances. The prescriber must still follow all laws applicable to Schedule II drugs by ensuring that the Schedule II prescription is complete with all the necessary information and bears the prescriber's signature and date in the prescriber's handwriting. In that the special circumstance Schedule II prescription is not on a security prescription, the Schedule II information must still be electronically transmitted on a weekly basis to the Department of Justice for these non-security form Schedule II prescriptions according to the CURES requirement.<sup>32</sup>

If a prescriber wishes to order a Schedule II drug using a regular prescription and properly indicating that it is for a terminally ill patient along with the "11159.2 Exemption" designation written or printed on the prescription, that prescription must be received by the pharmacist before it can be dispensed which differentiates this prescription from an emergency order for a Schedule II drug that can be called in by phone to the pharmacy and dispensed to the patient before the security prescription is sent to the pharmacy within 7 days by the prescriber.<sup>33</sup>

***ARE ORAL ORDERS FOR SCHEDULE II DRUGS  
ALLOWED FOR SPECIAL FACILITIES  
(E.G. SKILLED NURSING FACILITIES)?***

An oral or electronic order for a Schedule II controlled substance is allowed to be filled for such facilities

as licensed skilled nursing facilities, intermediate care facilities, or licensed hospice care facilities. If the prescription for a Schedule II drug is transmitted orally, the pharmacist shall reduce the prescription to writing in ink in his or her handwriting on a form developed by the pharmacy for this purpose.<sup>34</sup> If the prescription is transmitted electronically, the pharmacist shall produce, sign, and date a hard copy of the prescription.<sup>35</sup> The prescription order shall be properly endorsed by the pharmacist with the pharmacy's state license number, and the name and address of the pharmacy. In addition the licensed care facility shall forward to the dispensing pharmacist a copy of any signed telephone orders, chart orders, or related documentation substantiating each orally or electronically transmitted prescription transaction for a Schedule II prescription order.<sup>36</sup> The oral order for a Schedule II controlled substance may be provided to these facilities whether or not the controlled substance is needed on an emergency basis.<sup>37</sup>

Also note that the address of the special facility is to be used as the address of record for the patient.<sup>38</sup>

***CAN A PRESCRIPTION FOR A SCHEDULE II  
DRUG BE FILLED FOR LESS THAN  
THE QUANTITY SPECIFIED?***

There are generally three circumstances whereby a Schedule II prescription may be filled for less than the quantity specified on the face of the prescription. One such circumstance is where the pharmacy's supply of the Schedule II drug is less than the quantity requested on the prescription. The second situation is where the patient requests a smaller amount than what is indicated on the face of the prescription. The third arrangement is where the pharmacy receives a Schedule II prescription for a terminally ill patient who is confined to a licensed hospice or skilled nursing facility.



These situations may raise the question as to whether or not the patient is entitled to the remaining amount of the unfilled quantity at some later date.

Keep in mind that, as a general rule, “*NO PRESCRIPTON FOR A SCHEDULE II CONTROLLED SUBSTANCE MAY BE REFILLED.*”<sup>39</sup> However, the exceptions to this rule will be discussed immediately below:

*A. When the Pharmacy Does Not Have Sufficient Stock of the Schedule II Drug*

If the pharmacy does not have in stock the quantity of the Schedule II drug ordered, the pharmacist may fill the prescription with what he or she has, order the Schedule II drug, and fill the balance of the prescription within 72 hours of the first partial filling. The amount given must be noted on the prescription. If the remaining portion cannot be or is not filled within the 72 hour period, the pharmacist must contact the prescriber and request that a new security prescription for the Schedule II drug be initiated.<sup>40</sup>

*B. When the Patient Requests Less Than the Quantity Indicated*

When the patient requests less than the quantity indicated on the face of the Schedule II prescription, the physician must usually be notified before dispensing the smaller amount.<sup>41</sup> Once the smaller amount is provided per the patient's request, the remainder of the prescription may not be furnished. To provide the remainder or balance on a second filling of a Schedule II controlled substance would constitute a refill, and therefore would be in conflict with the rule that Schedule II drugs cannot be refilled.

As stated previously, the prescriber must be contacted if the Schedule II prescription is purposefully filled for less than the amount indicated on the face of the prescription. This requirement is in accordance with Section 1716 of the California Code of Regulations (Title 16), which states:<sup>42</sup>

*“Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber...”*

**C. Where the Patient is Terminally Ill and Confined to a Hospice Program or Skilled Nursing Facility**  
**(“The Partial Fill Rule”)**

There are, however, two circumstances that allow the pharmacist to partially fill a Schedule II prescription without contacting the prescriber. Such discretion for partial filling is allowed when:<sup>43</sup>

- The prescription is for an inpatient of a skilled nursing facility, or
- The prescription is for a terminally ill patient.

For a Schedule II controlled substance prescription to be placed within the partial fill category for skilled nursing facility patients who are terminally ill, the prescription must be filled, as noted previously, within 60 days following the date of issue as discussed above under the topic heading, *“HOW LONG MAY A SECURITY PRESCRIPTION FOR A SCHEDULE II CONTROLLED SUBSTANCE BE HELD BY THE PATIENT BEFORE FILLING?”* Further, all remainder amounts of the Schedule II prescription must also be filled within this 60 day period.<sup>44</sup>

In addition, the pharmacist must record the date and amount of each partial fill on the security prescription.

The prescription information must be forwarded via the CURES Program on a weekly basis once the prescription has been completely filled or when the patient is no longer on the medication. If the patient should die or be discontinued from the use of the drug before the prescription is completely filled, the remaining portion of the prescription is canceled and only what was received by the patient is to be transmitted via the CURES Program<sup>45</sup>

Also, the state Board requires that the partially filled prescription be signed by the person receiving the controlled substance at the skilled nursing or hospice facility.<sup>46</sup>

The rationale for this partial fill rule as stated previously appears to be predicated on the fact that the patient may not survive long enough to take the entire amount of the Schedule II drug ordered, and that it would not be wise to allow any extra doses of the drug to remain at the facility where the patient was cared for.

**D. How Might A Situation Be Handled Whereby A Patient  
Brings In A Schedule II Prescription  
For A 60 Day Supply And Insurance  
Will Pay For Only 30 Days?**

“The pharmacist may dispense a 30 day supply and bill the insurance carrier accordingly and dispense another 30 day supply in a second container to be paid for by the patient. The amount of drug supply may be divided in any number of ways, as long as there are separate labels for each container and the total does not exceed the amount written for on the prescription.”<sup>47</sup>

***MAY A SECURITY PRESCRIPTION FOR A  
SCHEDULE II DRUG BE REFILLED WITHOUT  
EXECUTING A NEW SECURITY PRESCRIPTION?***

As stated previously, the general rule is that no prescription for a Schedule II drug may be refilled unless the prescriber writes a new prescription on a new security prescription for the drug.<sup>48</sup> Again there is an exception to this, whereby increments from the total number requested on the face of the Schedule II drug prescription may be filled at various times within a 60 day period only pertains to the situation where the patient is terminally ill as discussed above.

***MAY A PHARMACY ORDER SCHEDULE II  
DRUGS FROM AN OUT-OF-STATE  
WHOLESALE OR SUPPLIER?***

A pharmacy may order Schedule II drugs from an out-of-state wholesaler, manufacturer, or other supplier as long as the pharmacy forwards a true and correct copy of the order, contract, or agreement for procurement of such Schedule II drugs to the State's Attorney General's office, via registered mail, within 24 hours of transmitting the order.<sup>49</sup>

***HOW IS DEA FORM 222 USED IN THE  
ORDERING OF SCHEDULE II DRUGS FROM A  
MANUFACTURER OR WHOLESALE?***

DEA Form 222 is the Department of Justice's order form for Schedule II drugs (also for Schedule I drugs being researched) to allow pharmacies to procure or purchase such substances from DEA-registered manufacturers, distributors or wholesalers.<sup>50</sup> Each time a DEA Form 222 is prepared by the pharmacy, it must be signed by the same person who signed the most recent DEA registration or by a person having power of attorney that has been previously submitted to the DEA.<sup>51</sup>

The following are important items to consider when executing a DEA Form 222:

- DEA Form 222 is used for both ordering and transferring Schedule II drugs. Each form is serially numbered and issued with the name, address, and registration number of the registrant.<sup>52</sup>
- Each DEA Form 222 is in triplicate format. An order may be filled-in by typewriter, pen or indelible pencil.<sup>53</sup> The top and middle copies must not be separated when preparing (leaving the carbon copy in place) and must be sent intact to the manufacturer or wholesaler.<sup>54</sup> Otherwise the order will be refused and returned to the pharmacy and a new order executed.

- An order will not be filled if either of the following circumstances exist:<sup>55</sup>
  - The order is not complete, legible, or properly prepared, executed, or endorsed.
  - The order shows any alteration, erasure, or change of any description.
- Only one item per line may be ordered. However, each item may be ordered in whatever quantity is required.
- Each order form has ten lines; thus, an order for Schedule II drugs may include up to ten items. After an order is prepared, the preparer must enter the number of line items ordered in a designated space on the form. This number must correspond exactly to the number of line item entries.
- The name and address of the Schedule II drug supplier must be entered on the form, along with the date and signature of the authorized registrant.
- If an error is made on the order form, the form may have to be voided. A form submitted with errors, erasures, or alterations will not be honored by the supplier and the form possibly returned.<sup>56</sup> If the form is returned by the supplier, an explanation should be reattached to the third copy and kept in the pharmacy.
- When the Schedule II drugs are received by the pharmacy from the supplier, the number of items and the date of receipt must be noted on the form by the purchasing registrant.
- The 3 copies of DEA Form 222 are disseminated as follows:<sup>57</sup>
  - *Copy one* (top copy) is retained by the supplier.
  - *Copy two* (middle copy) is sent by the supplier to the regional administrator of the DEA at the end of the month.
  - *Copy three* (bottom copy) is retained in the pharmacy and used to check-in the delivered order for Schedule II controlled substances along with the dates received.<sup>58</sup>



- Order forms are required to be kept as records, available for inspection, for a two year period. California requires that the order form record be kept for 3 years.<sup>59</sup>

***MAY DEA FORM 222 BE USED FOR THE RETURN  
TO THE SUPPLIER OR SALE TO OTHER PHARMACIES  
OF SCHEDULE II DRUGS?***

A pharmacy may execute an order on a DEA Form 222 for other purposes not associated with the purchasing of Schedule II drugs from a DEA registered manufacturer or wholesaler. Among those other purposes are the transfer of Schedule II drugs to a prescriber or another pharmacy, and the return of Schedule II drugs to a supplier.<sup>60</sup> There is one scenario involving the transfer of Schedule II substances which does not require the submission of a DEA Form 222, but does require written notification to the DEA and the pharmacy keeping inventory records of such transfers. This is where a pharmacy engages in a bulk sale of its Schedule II drugs (along with its other prescription drugs) to another pharmacy or to a new owner of the existing pharmacy.

The above circumstances are described in detail below:

- Transfer of Schedule II drugs to a prescriber or another pharmacy who is registered to dispense controlled substances requires a DEA Form 222. The form is used in exactly the manner described in the section directly above. If a prescriber orders the Schedule II drug from the pharmacy, the pharmacy serves as a supplier and must receive the first and second properly executed copies of the DEA Form 222 and process them as described in the preceding section, just as the wholesaler or manufacturer would.
- Return of Schedule II drugs to the supplier requires the supplier to furnish the pharmacy returning the drugs

with Copies 1 and 2 of the DEA Form 222. The pharmacy dates the form and records the Schedule II drugs being returned as line items with the quantity of each being returned. The pharmacy then retains Copy 1 for its records and sends Copy 2 to the regional administrator of the DEA. By following this procedure, the pharmacy acts as the supplier.<sup>61</sup>

- Discontinuance or transfer of business requires that the following information be provided to the DEA in writing and sent by registered mail at least 14 days in advance of the date of the proposed discontinuance or transfer:<sup>62</sup>
  - The name, address, registration number, and business activity of registrant transferring or discontinuing the business; and the same information, if a transfer is occurring, from the party acquiring the business.
  - Whether the business activities will be continued at the same location or transferred to another location.
  - The date when the transfer will occur.
  - On the date of transfer of the controlled substances, a complete inventory shall be taken of all controlled substances being transferred. The inventory records shall be maintained by both the transferor and the transferee.

#### ***POWER OF ATTORNEY (POA) FOR ORDERING SCHEDULE II CONTROLLED SUBSTANCES***

For community pharmacies, usually one individual, who does not have to be a pharmacist, is granted POA status by registering that individual as having the POA with the DEA. Only that individual with POA status can then assign POA status to another individual in his or her absence. The key point here is when ordering Schedule II controlled substances from the wholesaler, only that person with POA status may place that order.

In a hospital's ordering of Schedule II drugs from the wholesaler, generally POA status is granted by the DEA to the CEO or corporate officer of the hospital who signed the application for DEA registration. Again, only the registrant can then assign (or revoke) the POA to another person (such as a pharmacist, pharmacy technician, or pharmacy clerk) to act on the registrant's behalf for ordering Schedule II controlled substances and signing the DEA 222 forms. Once one of the pharmacy personnel with the assigned POA relinquishes that responsibility, the POA reverts back to the original signer of the DEA registration (e.g. CEO or a corporate officer), who may then reassign the POA to another responsible pharmacist employee. Only the registrant on the DEA license may grant or revoke a POA for anyone else. All POA assignments or reassignments must be forwarded to the DEA.

The power of attorney and notice of revocation form must be similar to the following format:<sup>63</sup>

**Power of Attorney For DEA Forms 222 and Electronic Orders**

\_\_\_\_\_  
(Name of Registrant)  
\_\_\_\_\_  
(Address of registrant)  
\_\_\_\_\_  
(DEA Registration Number)

I, \_\_\_\_\_ (name of person granting power), the undersigned, who am authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint \_\_\_\_\_ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for Forms 222 and to sign orders for Schedule II controlled substances, whether these orders be on Form 222 or electronic, in accordance with 21 USC \*28 and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

\_\_\_\_\_  
(Signature of person granting power)

I, \_\_\_\_\_ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

\_\_\_\_\_  
(Signature of attorney-in-fact)

Witnesses:

1. \_\_\_\_\_
2. \_\_\_\_\_

Signed and dated on the \_\_\_\_\_ day of \_\_\_\_\_ (year), at \_\_\_\_\_.

**Notice of Revocation**

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act. Written notice of this revocation has been given to the attorney-in-fact this same day.

\_\_\_\_\_  
(Signature of person revoking power)

Witnesses:

1 \_\_\_\_\_.

2 \_\_\_\_\_.

Signed and dated on the \_\_\_\_\_ day of \_\_\_\_\_ (year), at \_\_\_\_\_.

***MAY A CLINIC LICENSED TO DISPENSE DRUGS  
ALSO DISPENSE SCHEDULE II SUBSTANCES?***

A clinic licensed to dispense drugs may not order or dispense Schedule II controlled substances. However, a prescriber licensed to prescribe controlled substances may write prescriptions for Schedule II drugs (which must be filled at an outside pharmacy), and may also administer such drugs at the clinic.<sup>64</sup>

Schedule III, IV, and V controlled substances may be stored and dispensed pursuant to a properly executed prescription at the multispecialty clinics. Surgical clinics have a limited dispensing function. (See Chapter 9 for more details under the topic, “*Does a Clinic Require a Permit to Stock and Dispense Drugs?*”)

**REFERENCES TO CHAPTER 13**

1. Calif. Health & Safety Code, Sec. 11165[d]
2. *Ibid.* at Sec. 11190[e][1]
3. *Ibid.* at Sec. 11190[f][1]
4. *Ibid.* at Sec. 11161.5[a]
5. *Ibid.* at Sec. 11165.1
6. *Ibid.* at Sec. 11165.1[d] & Calif. Civil Code, Secs. 56.10 to 56.16 & 56.30
7. Calif. Health & Safety Code, Sec. 11165[d]
8. *Ibid.* at Sec. 11161.5[a]
9. *Ibid.* at Sec. 11161.5[f]
10. *Ibid.* at Sec. 11161.5[l][1][2]
11. *Ibid.* at Sec. 11162.1
12. *Ibid.* at Sec. 11162.1[c]
13. *Ibid.* at Sec. 11162.1[c][1][2]
14. *Ibid.* at Sec. 11162.1[c]
15. *Ibid.* at Sec. 11164[a][1]
16. *Ibid.* at Sec. 11164[a][b]
17. *Ibid.* at Sec. 11159.2
18. *Ibid.* at Sec. 11159.2[b]
19. *The Script* (a publication of the Calif. State Board of Pharmacy) January 2001 Edition, pg. 9
20. Calif. Health & Safety Code, Sec. 11164
21. *Ibid.* at Sec. 11164[b]
22. *Ibid.* at Sec. 11166
23. Title 16, Calif. Code of Regs., Sec. 1745[a][c]
24. Title 21, Fed. Code. Of Regs., Sec. 1304.04[f][1][h][1]
25. *Ibid.* at Sec. 1304.04[h][2]
26. Calif. Health & Safety Code, Sec. 11167
27. *Ibid.* at Sec. 11167[d]
28. *Ibid.* at Sec. 11159.2
29. *Ibid.* at Sec. 11159.2[b]
30. Title 16, Calif. Code of Regs., Sec. 1745[a][b]
31. *Ibid.* at Sec. 1745[c][d]
32. Calif. Health & Safety Code, Sec. 11165[d]
33. *Ibid.* at Sec. 11167[c][d]



34. *Ibid.* at Sec. 11167.5[a]
35. *Ibid.* at Sec. 11167.5[a]
36. *Ibid.* at Sec. 11167.5[a]
37. *Ibid.* at Sec. 11167.5[a]
38. *Ibid.* at Sec. 11167.5[a]
39. Title 21, Code of Fed. Regs. (CFR), Sec. 1306.12[a]
40. *Ibid.* at Sec. 1306.13[a] & Title 16, Calif. Code of Regs. Sec. 1745[d]
41. Title 16, Calif. Code of Regs., Sec. 1716
42. *Ibid.* at Sec. 1716
43. *Ibid.* at Sec. 1745[a]
44. *Ibid.* at 1745[c][1][3]
45. Calif. Health & Safety Code, Sec. 11165[d]
46. *The Script* (a publication of the Calif. State Board of Pharmacy), 1995 Edition, pg. 8
47. *The Script*, July 2001, pg. 8
48. Title 21, Code of Fed. Regs. (CFR), Sec. 1306.12[a] & Calif. Health & Safety Code, Sec. 11200[c]
49. Calif. Health & Safety Code, Sec. 11256
50. 21 USC 828[a] & 21 CFR, Secs. 1305.03, 1305.04 & 1305.06
51. 21 CFR, Secs. 1305.04 & 1305.05
52. *Ibid.* at Sec. 1305.11[d]
53. *Ibid.* at Sec. 1305.12[a]
54. *Ibid.* at Sec. 1305.15[d]
55. *Ibid.* at Sec. 1305.15[a]
56. *Ibid.* at Sec. 1305.15[a]
57. *Ibid.* at Sec. 1305.13[a][d]
58. *Ibid.* at Sec. 1305.13[e]
59. *Ibid.* at Sec. 1305.17[c] & Calif. Bus. & Prof. Code, Sec. 4105[c]
60. Title 21 CFR Secs. 1305.04[b], 1305.12, & 1305.13
61. *Ibid.* at Sec. 1307.12[a]
62. *Ibid.* at Sec. 1301.52
63. *Ibid.* at Sec. 1305.05
64. Calif. Bus. & Prof. Code, Sec. 4184



## CHAPTER 14

# RULES CONCERNING SCHEDULE III, IV AND V CONTROLLED SUBSTANCES

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***ARE PRESCRIPTION REQUIREMENTS FOR ALL  
SCHEDULE III, IV AND V CONTROLLED SUBSTANCES  
BASICALLY THE SAME?***

All Schedule III, IV and V controlled substances are basically treated in the same manner.<sup>1</sup> Any time a Schedule III, IV or V controlled substance prescription is executed the following general principles must be followed:

- All written prescriptions for Schedule III, IV, and V controlled substances prepared by the licensed prescriber must be on the special security prescription forms.<sup>2</sup>
- All usual information required on the prescription shall be in ink and in the handwriting of the prescriber or typewritten by the prescriber or his or her designee.<sup>3</sup> The prescriber must sign and date the prescription for the controlled substance in his or her handwriting.<sup>4</sup> Neither the prescriber's signature nor the date may be typed onto the prescription.
- Items such as the name and address of the prescriber, the degree held, and required DEA certification number may be typed or type-set on the prescription blank.<sup>5</sup> If the patient's address is missing from the prescription that may also be handwritten in or typed in by the pharmacist or the patient's address may be maintained in a readily retrievable form in the pharmacy.<sup>6</sup>
- If a prescriber orally orders or electronically transmits a Schedule III, IV or V prescription, the pharmacist or pharmacist intern shall reduce the prescription to writing on a regular prescription that will be signed and dated by the pharmacist filling or checking the prescription.<sup>7</sup> The address, telephone number, license classification, and federal registry number of the prescriber need not be reduced to writing if such information is readily retrievable in the pharmacy.<sup>8</sup>
- A retail or hospital pharmacy receiving an electronic transmission prescription or a computer entry prescription for a controlled substance classified as a



Schedule II, III, IV or V drug shall not be required to reduce that prescription to writing or to hard copy (it is assumed that this electronic receipt of the prescription is in association with the pharmacy and prescriber being registered under the “e-prescribing” program) unless the Board of Pharmacy or Department of Justice request the production of such a prescription in hard copy form, along with the name or identifier of the pharmacist who originally dispensed the requested controlled substance prescription.<sup>9</sup>

- If a Schedule III, IV, or V controlled substance prescription is written on a non-security prescription form, the pharmacist may treat that prescription as an oral or telephonic transmission. However, the pharmacist should not rely totally on the non-security prescription as an assurance of the validity or accuracy of the Schedule III, IV, or V controlled substance written prescription. The prescriber should be contacted to orally verify what was written for, and then record that validated information on the pharmacy’s own prescription forms in the same manner as an orally or telephonic transmitted controlled substance prescription would be handled.
- The name of any employee of the prescriber transmitting the prescription either orally or electronically on behalf of the prescriber must be noted on the prescription.<sup>10</sup>
- The prescriber may decide to transfer the Schedule III, IV, or V controlled prescription electronically. If so, the electronic prescription, unless it is transferred in accordance with the “e-prescribing” federal requirement, probably needs to be handled like a telephone order and the prescription information transcribed onto a prescription blank in the pharmacy. A telephone call to the prescriber’s office should also follow in regards to this electronic prescription transmission to ensure it is legitimate, with inclusion of the name or initials of person from the prescriber’s office that sent it.

- The pharmacist must ensure both the authenticity and integrity of each orally or electronically transmitted prescription so that it cannot be repudiated at some later date. If a prescription for a Schedule III, IV or V controlled substance is faxed, it must contain a telephone number so that the pharmacist may verify that the prescription came from the prescriber.<sup>11</sup>
- As noted in the previous chapter, Chapter 13, in regards to the CURES Program, Schedule III and IV as well as Schedule II controlled substance prescriptions must be reported to the Department of Justice within one week (7 days) after being filled.<sup>12</sup>

***CAN A NON-SECURITY PRESCRIPTION FORM BE USED TO DISPENSE ANY CONTROLLED SUBSTANCE FOR A TERMINALLY ILL PATIENT?***

The Health & Safety Code, Section 11159.2 that previously only allowed for a Schedule II Controlled Substance to be written on a non-security form prescription for purposes of providing the scheduled drug to a terminally ill patient now has been amended to allow for the other Scheduled Controlled Substances (Schedules III, IV, and V) to also be written for on a regular prescription for a terminally ill patient. The qualifying statement, “11159.2 Exemption” must also be written on the regular prescription that is not a security form for a terminally ill patient when prescribing the other controlled substances.<sup>13</sup>

***E-PRESCRIBING OF CONTROLLED SUBSTANCES***

The DEA Interim Final Rule took effect on June 1, 2010 formally allowing electronic prescribing of Schedule II, III, IV, and V controlled substances. In order to be in conformance with the rule established by the DEA, prescribers may prescribe and pharmacists may receive these electronic prescriptions for controlled substances when each have the necessary approved software and are certified

by an outside agency that meets the new requirements of the established regulations. The California Board of Pharmacy, working with the DEA, will help provide guidance to pharmacists on how they are to use the e-prescribing system and their responsibilities in ensuring compliance with the new rule. The implementation of this Interim Final Rule will provide for better controlled substance inventory tracking, and a more efficient manner in providing patients with their controlled substance therapy. Prescriptions for e-prescribed drugs will be easier to read and will hopefully decrease drug errors.

A prescriber may issue a prescription for a Schedule II, III, IV, or V controlled substance electronically if all of the following conditions are met:<sup>14</sup>

- The prescriber is registered with DEA to prescribe controlled substances.
- The prescriber uses an electronic prescription application that meets all of the applicable requirements.

A registered pharmacy may process electronic prescriptions for controlled substances only if all of the following conditions are met:<sup>15</sup>

- The pharmacy uses a pharmacy application that meets all of the applicable requirements.
- The prescription is in conformity with the requirements of the Act.

Listed below are various other requirements that must be followed by both the registered prescriber and the registered pharmacy engaged in the “E-prescribing” of controlled substance prescriptions:<sup>16</sup>

- Prescriber responsibilities:
  - The prescriber must maintain sole possession of the hard token provided by the DEA and the password or biometric information to be used in order to forward controlled substance prescriptions electronically to a registered pharmacy.

- If a prescriber is notified by a pharmacy that an electronic prescription was not successfully delivered, he or she must ensure that any paper or oral prescription issued as a replacement of the original electronic prescription indicates that the prescription was originally transmitted electronically to a particular pharmacy and that the transmission failed.
- The transmitted prescription must be electronically signed by the prescriber. The electronic prescription may allow the registered prescriber or his agent to enter data for a controlled substance prescription, provided that only the registrant prescriber may sign the prescription.<sup>17</sup>
- The prescriber has the same responsibilities when issuing prescriptions for controlled substances via electronic means as when issuing a paper or oral prescription.
- **Electronic prescription transmission:**<sup>18</sup>
  - The electronic prescription must be transmitted as soon as possible after the electronic signature of the prescriber is added, or the transmission may fail.
  - The electronic prescription application may print a prescription that has been transmitted only if the designated pharmacy notifies a practitioner that an electronic prescription was not successfully delivered to the designated pharmacy. If this occurs, the electronic prescription application may print the prescription for the practitioner's manual signature. The printed prescription must include information noting that the prescription was originally transmitted electronically to [name of the specific pharmacy] on [date/time] and that transmission failed.
  - The electronic prescription application must not allow the transmission of an electronic prescription if an original prescription was printed prior to attempted transmission.



- The contents of the prescription required must not be altered during transmission between the practitioner and pharmacy. Any change to the content during transmission, including truncation or removal of data, will render the electronic prescription invalid.
- An electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (*e.g.*, facsimile) for transmission.
- Pharmacy responsibilities:<sup>19</sup>
  - The receiving pharmacy must also have an authorization system in place to receive the prescription electronically and provide a digital signature upon receiving and filling the controlled substance prescription. Therefore, “e-prescription” transmissions can only be sent and legitimately received from “e-prescription” prescribers by a pharmacy that has a certified system in place to receive such prescriptions.
  - When a prescription is received electronically, the prescription and all required annotations must be retained electronically. In California, the prescription must be retained for 3 years from the last date an entry is made on it.
  - When a pharmacist receives a paper or oral prescription that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist must check its records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist must mark one as void.

The DEA Office of Diversion Control on March 31, 2010 provided a series of questions with answers that addresses the basics of Electronic Prescriptions for



**Controlled Substances.** Provided below is a recap of some of those questions with the answers for those matters that concern the practice of pharmacy using this electronic prescribing system.<sup>20</sup>

**Q. Is the use of electronic prescriptions for controlled substances mandatory?**

*A. No, the new regulations do not mandate that practitioners prescribe controlled substances using only electronic prescriptions. Nor do they require pharmacies to accept electronic prescriptions for controlled substances for dispensing. Whether a practitioner or pharmacy uses electronic prescriptions for controlled substances is voluntary from DEA's perspective. Prescribing practitioners are still able to write, and manually sign, prescriptions for schedule II, III, IV, and V controlled substances and pharmacies are still able to dispense controlled substances based on those written prescriptions. Oral prescriptions remain valid for schedule III, IV, and V controlled substances.*

**Q. When can a pharmacy start processing electronic prescriptions for controlled substances?**

*A. A pharmacy will be able to process electronic controlled substance prescriptions only when the pharmacy application the pharmacy is using complies with the requirements in the interim final rule.*

**Q. How will a practitioner or pharmacy be able to determine that an application complies with DEA's rule?**

*A. The application provider must either hire a qualified third party to audit the application or have the application reviewed and certified by an approved certification body. The auditor or certification body will issue a report that states whether the application complies with DEA's requirements and whether there are any limitations on its use for controlled substance prescriptions. (A limited set of prescriptions require information that may need revision of the basic prescription standard before they can be reliably accommodated.) The application provider must provide a copy of the report to practitioners or pharmacies*

*to allow them to determine whether the application is compliant.*

**Q.** As a pharmacy, until I have received an audit/certification report from my application provider indicating that the application meets DEA's requirements, how can I use my pharmacy application to process controlled substances prescriptions?

*A. A pharmacy cannot process electronic prescriptions for controlled substances until its pharmacy application provider obtains a third party audit or certification review that determines that the application complies with DEA's requirements and the application provider provides the audit/certification report to the pharmacy. The pharmacy may continue to use its pharmacy application to store and process information from paper or oral controlled substances prescriptions it receives, but the paper records must be retained.*

**Q.** Is it permissible to have a staff person in the practitioner's office complete all of the required information for a controlled substance prescription and then have the practitioner sign and authorize the transmission of the prescription?

*A. Yes, however, if an agent of the practitioner enters information at the practitioner's direction prior to the practitioner reviewing and approving the information, the practitioner is responsible in the event the prescription does not conform in all essential respects to the law and regulations.*

**Q.** If transmission of an electronic prescription fails, may the intermediary convert the electronic prescription to another form (e.g. facsimile) for transmission?

*A. No, an electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. If an intermediary cannot complete a transmission of a controlled substance prescription, the intermediary must notify the practitioner. Under such circumstances, if the prescription is for a schedule III, IV, or V controlled substance, the practitioner can print the prescription, manually sign it, and fax the prescription directly to the pharmacy. This prescription must indicate that it*

*was originally transmitted to, and provide the name of, a specific pharmacy, the date and time of transmission, and the fact that the electronic transmission failed.*

**Q. What are the restrictions regarding alteration of a prescription during transmission?**

*A. The (DEA-required) contents of a prescription shall not be altered during transmission between the practitioner and pharmacy. However, this requirement only applies to the content (not the electronic format used to transmit the prescription). This requirement applies to actions by intermediaries. It does not apply to changes that occur after receipt at the pharmacy. Changes made by the pharmacy are governed by the same laws and regulations that apply to paper prescriptions.*

**Q. What should a pharmacist do if he receives a paper or oral prescription that was originally transmitted electronically to the pharmacy?**

*A. The pharmacist must check the pharmacy records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist must mark one as void.*

**Q. What should a pharmacist do if he receives a paper or oral prescription that indicates that it was originally transmitted electronically to another pharmacy?**

*A. The pharmacist must check with the other pharmacy to determine whether the prescription was received and dispensed. If the pharmacy that received the original electronic prescription had not dispensed the prescription, that pharmacy must mark the electronic version as void or canceled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void.*

**Q. What are the DEA requirements regarding the storage of electronic prescription records?**

*A. Once a prescription is created electronically, all records of the prescription must be retained electronically. As is the case with paper prescription records, electronic controlled substance prescription records must be kept for a minimum period of two years. (While this is a federal standard, California requires prescription records to be kept three years).*

**Q. When must a third-party audit or certification be conducted?**

*A. The third-party audit or certification must be conducted before the electronic prescription application is used to sign or transmit electronic prescriptions for controlled substances, or before the pharmacy application is used to process electronic prescriptions for controlled substances, respectively. Thereafter, a third-party audit or certification must be conducted whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.*

***IN WHAT MAJOR WAY DOES A PRESCRIPTION FOR A SCHEDULE V DRUG DIFFER FROM A PRESCRIPTION FOR A SCHEDULE II, III OR IV DRUG?***

For the most part, prescriptions for Schedule V drugs are usually for conditions involving a cough or for the management of diarrhea. As noted in Chapter 12, Scheduled drugs may contain codeine, a codeine derivative, or tincture of opium in combination with a non-scheduled drug.<sup>21</sup> Because of the types of medical conditions that Schedule V controlled substances are intended for, it is not uncommon that a person with a cough or diarrhea could transmit it to other members of a family. It is for this reason that the law allows for one prescription for a Schedule V drug to be written for more than one person in the same family with the same medical need.<sup>22</sup> Only Schedule V prescriptions, in comparison to the other Schedules, may be executed in this manner. There is probably an exception

to this rule however; when the recently added Schedule V drug pregabalin (*Lyrica*®) is used to relieve neuropathic pain, it is only to be written for an individual patient.

***WHAT ARE THE REFILL ALLOWANCES  
FOR SCHEDULE III AND IV CONTROLLED  
SUBSTANCE PRESCRIPTIONS?***

A prescription for a Schedule III or IV controlled substance may be refilled up to five times. Any refills indicated on such prescriptions must be filled within a 6 month period from the date the prescription is written.<sup>23</sup> If the patient is to be continued on the same controlled substance after all the allowable refills are used, and the prescriber is called and authorizes a continuation of the prescription, then the pharmacist must execute a new prescription with any additional refills (up to five) that would cover a subsequent 6 month period.

Furthermore, the refills on a Schedule III or IV controlled substance prescription may not exceed a 120 day supply.<sup>24</sup> Thus, if a prescription is written for 100 Ambien (zolpidem tartrate) 5 mg tablets, a Schedule IV controlled substance, with directions of one tablet at bedtime and having 5 refills, only the original and one refill may be processed without calling the physician. Although the first refill only represents 100 days, a subsequent refill would extend it to 200 days, or 80 days beyond the limits of what the law allows. In regards to this scenario, after the first refill the prescriber would have to be contacted for a continuance, and such continuance, if approved, would have to be reduced to writing as a new prescription.

***IF THERE ARE NO REFILLS ON A SCHEDULE III,  
IV, OR V PRESCRIPTION, MAY AN EMERGENCY  
SUPPLY BE GIVEN TO THE PATIENT IF THE  
PRESCRIBER IS UNAVAILABLE?***

The pharmacist is afforded discretion in the refilling of a Schedule III, IV, or V controlled substance prescription



if the prescriber is unavailable to authorize a subsequent renewal of the prescription. This allowance is addressed in the following statute:<sup>25</sup>

*CA Health & Safety Code, Sec. 11201*

*“A prescription for a controlled substance, except those appearing in Schedule II, may be refilled without the prescriber’s authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist’s professional judgment, failure to refill the prescription might present an immediate hazard to the patient’s health and welfare or might result in intense suffering.”*<sup>26</sup>

The statute also states that the pharmacist may only refill the Scheduled drug prescription for a reasonable amount sufficient to maintain the patient until the prescriber can be contacted.<sup>27</sup> The pharmacist shall still make every reasonable effort to contact the prescriber to receive approval on a refill.

The pharmacist must inform the prescriber as soon as possible regarding the action he or she took in providing the patient with a reasonable supply of the drug. In addition, the pharmacist shall maintain the following information on the reverse side of the prescription:<sup>28</sup>

- The date and quantity of the refill.
- That the prescriber was unavailable.
- The basis for the pharmacist’s judgment in refilling the prescription without the prescriber’s authorization.

It is also the responsibility of the pharmacist to inform the patient that the prescription was refilled without the prescriber’s authorization because of his or her unavailability and that, in the pharmacist’s professional judgment, failure to provide the drug might result in harm or intense suffering.<sup>29</sup>

***HOW ARE PRESCRIPTIONS FOR SCHEDULE II, III, IV  
AND V DRUGS TO BE FILED IN THE PHARMACY AFTER  
BEING FILLED?***

Even though California now requires that prescribers use the uniform security prescription blank to write for all Scheduled control substances, it is still required that all Schedule II controlled substance prescriptions after they are filled be filed separately.<sup>30</sup> Schedule III, IV, and V controlled prescriptions may be filed together separately, or integrated into the nonscheduled prescription record files.

If the filled Schedule III, IV, and V controlled substance prescriptions are to be filed with the nonscheduled prescriptions, they must each have stamped upon them a one inch red letter "C" in the lower right hand corner of the filled prescription in order that the controlled substance prescriptions can be easily identified among the nonscheduled prescriptions for retrieval purposes.<sup>31</sup> The red one inch "C" does not have to be stamped on the Schedule III, IV, or V prescriptions if an electronic filing system is used.

***MAY AN OUT-OF-STATE PRESCRIPTION FOR  
A CONTROLLED SUBSTANCE BE BOTH FILLED  
AND REFILLED IN CALIFORNIA?***

Concerning the filling of out-of-state prescriptions for Schedule II controlled substance prescriptions, the law appears to allow for only one exception and that is if the prescription is written by a prescriber from another state it may be filled by a California pharmacy for delivery to a patient in another state provided the prescription conforms to the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.<sup>32</sup> This allowance appears to accommodate patients who wish to have their prescriptions filled by out-of-state mail order operations. Since California requires Schedule II controlled substance prescriptions to be written on special security

forms exclusively, except for emergency phone-in (including electronic E-prescribing transmissions) or being prescribed pursuant to the terminally ill patient requirement (see Chapter 13 for the details on how these two methods deviate from the direct submission of a security form prescription), the writing of Schedule II controlled substance prescriptions will only be acceptable if prepared by a California licensed prescriber who has the authority to write for these drugs.

For a California resident, a pharmacist may fill an out-of-state prescription for a Schedule III, IV or V controlled substance if the licensed prescriber telephones in the prescription to the California pharmacy and is a DEA registrant, and may also refill such prescriptions within the 6 month period from the date written if refills are authorized.<sup>33</sup> However, based upon California law, the out-of-state prescriber who writes for a Schedule III, IV, or V prescription for a California residence, will be held to the same standard of writing such prescriptions on the special ordered security forms required by this State's laws.<sup>34</sup> Perhaps the way around this for the out-of-state prescriber who does not have the security prescription forms, is to phone-in or electronically transfer the prescription information for Schedule III, IV, or V controlled substances to the California pharmacy.<sup>35</sup>

An out-of-state prescriber may also write for a Schedule II controlled substance to be filled in a California pharmacy if that prescription is written on a California controlled substance security form prescription that the out-of-state prescribers needs to obtain if they plan to write Schedule II controlled substance prescriptions for California residents.<sup>36</sup>

A pharmacist who fills any out-of-state prescription must ensure that it is legitimate. To determine authenticity the prescriber may have to be telephoned.

***MAY PRESCRIPTIONS FOR CONTROLLED  
SUBSTANCES BE MAILED TO PATIENTS IN  
CALIFORNIA AND OUT-OF-STATE?***

Prior to 1995, restrictions existed that prevented narcotics or cocaine from being mailed by means of the federal mail system, but allowed other categories of scheduled drugs to be mailed via the federal mail system. The Postal Regulations involved have been amended to allow for the U.S. mail service to carry prescription medications that contain any controlled substance including narcotics and cocaine.<sup>37</sup> Controlled substances may be mailed through the U.S. Postal Service if the pharmacy is DEA registered and the following conditions are met:<sup>38</sup>

1. For a prescription medication, the inner container is labeled to show the name and address of the pharmacy and the prescriber, and the outside properly wrapped in plain paper.
2. The outside wrapper or container is free of markings that would indicate the nature of the contents.

Before the amended restriction, pharmacies would generally get around the mailing of narcotics and cocaine by using non-federal mailing agencies such as the United Parcel Service (UPS).

Prescriptions for controlled substances may not be delivered or shipped to individuals in other countries without proper authorization. Any such delivery or shipment is an export under the CSA and cannot be conducted unless the person sending the controlled substance:

1. Has registered with the DEA as an "exporter."<sup>39</sup>
2. Has obtained the necessary permit(s), or submitted the necessary declaration(s) for export.<sup>40</sup>

***HOW DO YOU DETERMINE THE AUTHENTICITY OF  
A PRESCRIBER'S FEDERAL CONTROLLED SUBSTANCE  
REGISTRATION NUMBER?***

There is a formula that is used to determine the validity of a prescriber's federal controlled substance registration number. The following example outlines the steps in determining the authenticity of this federal registration number:

*Example Registration Number: AL 8010869*

*Step 1:* *Add up all of the numbers that are in the odd numbered sequence, except for the last digit (do not add the "9").*

$$8 + 1 + 8 = 17$$

*Step 2:* *Add up all of the numbers that are in the even numbered sequence and multiply the result by 2.*

$$0 + 0 + 6 = 6 \times 2 = 12$$

*Step 3:* *Add the sum of the odd sequenced numbers from Step 1 to the sum of the even sequenced numbers from Step 2.*

$$17 + 12 = 29$$

*Step 4:* *The last digit (9) in the added total from Step 3 should be the same number as the last number in the federal registration number (which is 9). If the two numbers are the same, this suggests that the federal registration number is authentic.*



***HOW FREQUENTLY ARE YOU  
REQUIRED TO TAKE AN INVENTORY OF YOUR  
SCHEDULE II, III, IV AND V DRUGS?***

It is required by federal law that every pharmacy have a complete and accurate record, every two years, of all Scheduled controlled substances still in its stock.<sup>41</sup> The following requirements must be met in the taking of this inventory:<sup>42</sup>

- An accurate accounting of all Schedule II controlled substances in stock must be made on the day of the inventory. Whereas, for Schedule III, IV and V controlled substances an estimate count or measure may be taken, unless the drug container holds more than 1000 units of the drug, then an exact count must be taken if the container has been opened.
- A biennial inventory must be taken. After the initial inventory, the pharmacy shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.<sup>43</sup> The record of the inventory must be kept at the pharmacy and produced if requested during an inspection by the State Board of Pharmacy or by the DEA.
- The information required for the inventory should contain the following:<sup>44</sup>
  - Name, address and DEA registration number of the registrant.
  - The date and time the inventory is taken.
  - Signature of person(s) taking the inventory.
  - The name of each controlled substance inventoried (along with dosage form, strength, number of units or volume, and the number of commercial containers).
  - The inventory taken must be maintained for three years and made available for inspection by authorized personnel. The inventory is not sent to the DEA offices, but is kept within the pharmacy.<sup>45</sup>

***MAY SCHEDULE III, IV OR V  
CONTROLLED SUBSTANCES BE WRITTEN  
FOR BY USING A MULTIPLE CHECK-OFF  
PRESCRIPTION BLANK?***

A pharmacist may not dispense a controlled substance issued on a regular preprinted, multiple check-off prescription blank.<sup>46</sup> However, if the Schedule II, III, IV, or V controlled substances (or any combination of these) are preprinted or written in on a special security form used exclusively for the issuance of multiple controlled substances, then these drugs may be filled as long as the number of Schedule II, III, IV and V controlled substances ordered and filled is noted on the prescription.

Since the Schedule II controlled substance prescriptions must be filed separately as a hard copy, it is suggested that the pharmacist make a copy of the prescription containing multiple controlled substances ordered, and file one copy with the Schedule II controlled substances, and the other copy with either the III, IV, and V controlled substance records if kept separate, or with the nonscheduled prescription records (marking the prescriptions with the one inch red "C" in the lower right hand corner if integrated into the nonscheduled prescription record files).

***UNDER WHAT CIRCUMSTANCES MAY A  
PRESCRIBER NOT ORDER A PRESCRIPTION FOR A  
CONTROLLED SUBSTANCE?***

A prescriber may not write or electronically transmit an order for a prescription for a controlled substance if any of the following conditions exist:

- The prescriber does not possess an active or valid federal registry permit or number.
  - The prescriber intends to prescribe, administer, or furnish the controlled substance to himself or herself.<sup>47</sup>
- However, the law does not appear to prevent a

prescriber from prescribing, administering, or furnishing a controlled substance for a family member provided there is a physician-patient relationship, the drug is being prescribed for a legitimate medical purpose, and a good faith examination was performed. It is important to note that if the pharmacist has knowledge that the prescriber is in fact writing the prescription for his or her use by using another's name, this illegal act will also impute liability onto the pharmacist who fills the prescription.

- The prescribing of the controlled substance for a medical problem that would be considered outside of the scope of the prescriber's practice.
- An order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research.<sup>48</sup>
- An order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized methadone maintenance program, for the purpose of providing the user with controlled substances to maintain their addiction or habit.<sup>49</sup>

### ***MAY A PRESCRIBER ANTEDATE OR POSTDATE A PRESCRIPTION FOR CONTROLLED SUBSTANCES?***

The antedating or postdating of any prescription for a controlled substance is illegal.<sup>50</sup> This requirement not only applies to controlled substance prescription, but also applies to nonscheduled drug prescriptions as well. However, a prescriber can write on a prescription to dispense the controlled substance on a date subsequent to the date on the prescription which would represent the day it was written. As an example, the prescriber writes the prescription for the controlled substance on January 15, 20xx, but indicates that he or she does not want the patient to start the medication until February 15, 20xx. Thus, the pharmacist may delay the dispensing of the medication based upon the date requested by the prescriber for providing it to the patient.

***WHAT REQUIREMENTS ARE THERE FOR THE  
DISPOSAL OF CONTROLLED SUBSTANCES?***

Where there is an intent to dispose of controlled substances, a *DEA Form 41* should be requested from the regional DEA office. Upon receipt of *DEA Form 41* all controlled substances to be disposed of must be listed and that the 3 copies of this completed form be sent to the regional DEA director. The regional director of special DEA agent upon receipt of the Form will provide instructions on how to proceed with the disposal.<sup>51</sup>

There are two major methods in which Scheduled controlled substances may be disposed of once a DEA official is contacted for advisement:

- Provide a controlled substance inventory form (*DEA Form 41*) to accompany the drugs to be disposed which are to be mailed to a designated disposal site within the State.
- Recommend that the manufacturer or wholesaler be contacted to determine their policy on the return of controlled substances to be disposed of. Usually, if the drug container has not been open, the manufacturer or wholesaler might allow for the return, and possibly issue credit. If the return of a controlled substance is authorized, again there are federal forms provided by the manufacturer or wholesaler that must be completed to ensure for proper credit and accountability.

***IS THERE AN AUXILIARY WARNING THAT MUST BE  
AFFIXED OR ACCOMPANY THE  
PRESCRIPTION VIAL THAT CONTAINS  
A PRESCRIBED CONTROLLED SUBSTANCE?***

Any time that a Schedule II, III, IV or V controlled substance is dispensed to a patient, the federal laws require that the following information be conveyed in the following words or words of similar import to the patient, ***"IT IS A CRIME TO TRANSFER THIS DRUG TO ANY PERSON***



**OTHER THAN THE PATIENT FOR WHOM THE DRUG WAS PRESCRIBED.”<sup>52</sup>** An auxiliary label containing this information should be affixed to the prescription container containing the controlled substance.

***MAY A PHARMACIST OR HIS/HER DESIGNEE CARRY AND FURNISH PARENTERAL CONTROLLED SUBSTANCES TO A PATIENT AT HOME?***

A pharmacist or his/her designee may only carry and furnish controlled substances for parenteral therapy to a patient at their home if the controlled substance is properly labeled and has the name of the patient who will receive the drug. However, the pharmacist may carry and furnish nonscheduled prescription drugs and devices for parenteral therapy, labeled or not labeled, as long as it is a nonscheduled drug or device that is currently prescribed for the patient.<sup>53</sup>

***MAY A PHARMACIST DISPENSE A CONTROLLED SUBSTANCE TO A PATIENT FOR AN ADDICTION PROBLEM?***

Neither may the physician prescribe a controlled substance for a patient with an addiction problem, nor may the pharmacist dispense a controlled substance with knowledge that the patient is using the drug exclusively for an addiction problem.<sup>54</sup> However, both prescribing and dispensing a controlled substance (specifically methadone) for an addiction to heroin or other narcotics is allowed under special conditions associated with an “Authorized Addiction Treatment Program” pursuant to Section 11217 of the California Health and Safety Codes (see the discussion that follows). Also the use of buprenorphine for treating Schedule III, IV, or V addictions by physicians is allowed under special conditions without requiring special government registration (see below).<sup>55</sup>



Often in practice, a pharmacist may not wish to dispense a controlled substance prescription drug that he or she believes has caused a patient to become addicted. While this may be more an ethical issue than a legal matter, keep in mind that you as a pharmacist may dispense such a drug even though the patient shows signs of addiction if the main purpose of the drug is to treat a known medical condition other than the addiction.

### ***ARE THERE SPECIAL PROGRAMS TO TREAT THOSE ADDICTED TO NARCOTICS?***

As suggested previously, “a prescriber may only prescribe for, furnish to, or administer controlled substances to his/her patient when the patient is suffering from a disease, ailment, injury, or infirmities attendant upon old age, other than addiction to a controlled substance.”<sup>56</sup> Furthermore, a pharmacist shall not knowingly fill a controlled substance prescription for a patient who is taking such medications to support a drug habit or addiction, unless such a prescription is sanctioned under special conditions or programs established by the State of California to allow for the treatment of such addicts.<sup>57</sup>

In the provision of treatment for narcotic drug addiction, such patients may only be treated at the following facilities:<sup>58</sup>

- An institution approved by the State Department of Mental Health, and where the patient is at all times kept under restraint and control.
- A city or county jail.
- A state prison.
- A facility licensed by the State Department of Mental Health.
- A state or county hospital.
- A facility licensed by the State Department of Alcohol and Drug Programs.
- Other types of facilities may be licensed by the Department of Mental Health as the need arises.

The major drug used in the treatment of those addicted to narcotics is methadone. However, other drugs such as opium, morphine, hydromorphone (Dilaudid), and meperidine (Demerol) may also be used.<sup>59</sup> Regarding these drugs, there have been limits to how much of each drug can be provided the addicted patient. Usually during the first 15 days of treatment, the addict shall not receive anymore than the following per day:<sup>60</sup>

- Eight grains of opium.
- Four grains of morphine.
- Six grains of Pantropon.
- One grain of Dilaudid.
- Four hundred milligrams of isonipecaine (Demerol)

After 15 days of the above treatment, the addict-patient shall not receive more than the following of anyone drug on a daily basis:<sup>61</sup>

- Four grains of opium.
- Two grains of morphine.
- Three grains of Pantopon.
- One-half grain of Dilaudid.
- Two hundred milligrams of isonipecaine (Demerol).

At the end of 30 days from the first treatment, the provided controlled substance used to treat the addiction, except for methadone, shall be discontinued. Methadone and levoalphacetylmethadol (LAAM) may be used beyond the 30 day period.<sup>62</sup>

The following persons may be involved in the administration of a controlled substance to treat a narcotic addict when acting under the authority of a qualified prescriber who is allowed to provide such treatment for addiction:<sup>63</sup>

- A registered nurse.
- A physician's assistant.
- A licensed pharmacist (oral administration only).
- A psychiatric technician (oral administration only).
- A licensed vocational nurse (oral administration only).

***MAY A PHARMACIST DISPENSE A SPECIFIC DRUG TO TREAT ADDICTION EVEN THOUGH NOT A PART OF A STATE GOVERNMENT PROGRAM?***

The drugs *Suboxone*® (buprenorphine/naloxone) and *Subutex*® (buprenorphine) may be dispensed by a pharmacist under the following conditions to treat addiction:<sup>64</sup>

- Physician who prescribes these drugs must have completed not less than 8 hours of authorized training in management of opioid-dependent patients addicted to Schedule III through V controlled substances.
- Physicians who have completed above course can receive from the DEA a second DEA number with number identical to their regular DEA number except the “A” or “B” at the beginning of the number will be replaced by an “X.” This second DEA “X” number allows the prescription to be filled by the pharmacist.
- This certification allows a physician to treat only 100 patients at one time.
- The prescribing or furnishing of these drugs may not be delegated pursuant to a protocol to a nurse practitioner (NP) or a physician assistant (PA).

***MAY AN OFFICER OF THE LAW TAKE A PRESCRIPTION RECORD THAT WAS USED TO FILL A PRESCRIPTION FOR A CONTROLLED SUBSTANCE?***

In order for an officer of the law (State Board of Pharmacy inspector, peace officer, agent of the Attorney General’s office, or DEA officer) to gather evidence during a criminal investigation, that officer may remove prescription records from your files. If such prescription records are to be removed and taken, a receipt for such records must be provided to you and maintained in your pharmacy.<sup>65</sup> Also, it is a good idea to make photocopies of all prescription records removed and taken.

**WHAT STANDARDS MUST BE FOLLOWED IN  
ASSOCIATION WITH AN "INJECTION CARD SYSTEM"  
PROGRAM?**

The "Injection Card System" enables a facility to authorize an outpatient to receive injections of controlled substances at that facility. Injections are authorized by written order of a prescriber and are recorded on a card, which is retained at the facility where the injections are administered.<sup>66</sup>

The "Injection Card" shall contain, at a minimum, the following information.<sup>67</sup>

- Date of authorization.
- Number and frequency of injections authorized.
- Name of drug including strength authorized.
- Name of prescriber(s).
- Date and time of each injection.
- Signature of person administering injection.

A facility employing the "Injection Card System" shall establish a written protocol describing the system and the procedures used in the provision of injections to patients. The protocol shall be developed by a team of at least one physician, one nurse, and one pharmacist, and shall include the following:<sup>68</sup>

- Identification of the drugs to be included in the "Injection Card System."
- Distinction among classes of drugs.
- Periodic review of the system to monitor its effectiveness.
- Determination of whether each drug in the system requires that a physician be physically present during the injection, or readily available.
- A method of recording which allows for:
  - Immediate entry of each injection into the patient's medical record.
  - Identification of any pattern of drug abuse by the patient and/or potential adverse drug interactions.

- Discontinuing of the written prescriber's order authorizing the injections should any of the above problems occur.
- Retention of the "injection card" by the facility at all times.
- Evaluation procedure to determine whether each patient is a suitable subject to be using the system.
- Ongoing medical evaluation of the patient's response to the system.
- All "cards" shall become a permanent part of the patient's medical record within 15 days from the date the last authorized dose is administered.



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5. *Ibid.* at Sec. 11164[a][1]
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11. *The Script* (publication of the Calif. State Board of Pharmacy), October 2001, pg. 8
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37. 39 Code of Fed. Regs. (CFR), Secs. 111.1, 111.2, & 111.3
38. U.S. Dept. of Justice, DEA Office of Diversion Control, *Pharmacist's Manual, Section XIII, "US Postal Service Mailing Requirements For Controlled Substances."*
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40. *Ibid.* at Secs. 1312 or 1313
41. *Ibid.* at Sec. 1304.11[c]
42. *Ibid.* at Sec. 1304.11[e][3]
43. *Ibid.* at Sec. 1304.11[c]
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45. *Ibid.* at Sec. 1304.04[a]
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47. Calif. Health & Safety Code, Sec. 11170
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## CHAPTER 15

### ***SIX NEW LAWS RECENTLY PASSED BY THE CALIFORNIA LEGISLATURE AND APPROVED BY THE GOVERNOR***

Of concern to California pharmacy practitioners are six new laws passed during this year's legislative session and approved by the Governor. These laws will become effective January 1, 2013.

#### **Ninety Day Prescription Drug Supply (SB 1301, Calif. Bus. & Prof. Code, Sec. 4064.5)**

A pharmacist will now be allowed to dispense up to a 90 day supply of drug on a prescription if the patient has first received a 30 day supply of the drug written as such. If refills are noted on the prescription, then the patient may be issued up to a 90 day supply upon a subsequent filling of the prescription without contacting the prescriber, and as long as the prescriber has not indicated that such a future supply cannot be given. This provision would not apply to either controlled substance nor psychotropic prescription medications. It appears that allowing this increase in amount after the first filling will cost the patient less money per each unit of drug, will lengthen the period before the patient needs to return for a refill, and will hopefully be consistent with the insurance companies policy on providing a drug for a longer period that is most likely to be used in a chronic condition.



**Prescription Audits Done By Health Benefit Plans  
And Insurers**

**(SB 1195, Calif. Bus. & Prof. Code, Sec. 4430)**

Existing law requires that health care service plan contracts and health insurance policies that provide coverage for specified benefits such as prescription costs incurred by patients to contain provisions requiring a fast, fair, and cost-effective dispute resolution mechanism. This law would place certain conditions on the service plan and health insurance providers such as requiring the service plan and health insurance providers to state clearly in its contract with the pharmacy, a process for appealing the findings of an audit report. However, this law would provide that if an identified discrepancy for a single audit exceeds \$30,000, future payments to the pharmacy in excess of \$30,000 may be withheld pending adjudication of the appeal without allowing interest to be accrued to the amount of money withheld. Further, and perhaps a major point in this law, if the service plan or health insurance provider uses an extrapolation process in calculating penalties to be recouped from a pharmacy, the pharmacy shall have an opportunity to both receive evidence of how the service plan or insurance provider came to its calculation determination, and that the pharmacy have an opportunity to provide evidence of how it arrived at its requests for payment. Also this law would prohibit a pharmacy from being subject to recoupment of funds for a clerical or recordkeeping error.

**CLIA Waivers For Pharmacists Performing Certain Routine  
Laboratory Tests**

**(SB 1481, Calif. Bus. & Prof. Code Amended Sec. 4052.4)**

This bill would exempt from clinical laboratory licensing requirements and regulations, specified tests

performed by a pharmacist in a community pharmacy. The pharmacy must obtain a CLIA certificate of waiver and a registration from the State Department of Public Health in order to perform specific tests. Tests deemed CLIA (Clinical Laboratory Improvement Amendments of 1988) waived are those tests approved by the FDA as over-the-counter tests. Proponents believe this measure will result in greater access to safe, simple and economic tests that will play a crucial role in improving drug therapy, and improve patient health. As more patient testing agents are made available on the market, this will provide the pharmacist with the opportunity to test patients for various disorders allowing them to do tests that the patients could do for themselves, but opted not to.

**Hospital Pharmacy Centralized Drug Preparation And Drug  
Barcoding**

**(AB 377, Calif. Bus. & Prof. Code Adding Sec. 4128)**

Allows a group of hospitals, having a single ownership, to have a centralized hospital packaging pharmacy operation both compound medications and prepare unit dose packaging for its patients. The law would require that all unit doses prepared at the centralized pharmacy must contain barcodes that are to be read at the inpatient's bedside to ensure that the patient will be receiving the correct medication. This centralized packaging and compounding pharmacy is to provide packaged and prepared medications to only hospital operations that are mutually owned and are within a 75 mile radius of each other. The centralized pharmacy operation must obtain a specialty license from the Board of Pharmacy that is to be renewed annually.

**Pharmacists Involved In A Civil Suit Influencing Plaintiff  
Patients Not To File A Complaint With The Board of  
Pharmacy**

**(AB 2570, Adds to Calif. Bus. & Prof. Code, Sec. 143.5)**

This law would prohibit a licensee who is regulated by the Department of Consumer Affairs or various Boards, as specified, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the Board, or that requires the other party to withdraw a complaint from the Board.

**Registered Nurses In Licensed Clinics  
Dispensing Drugs**

**(AB 2348, Calif. Bus. & Prof. Code Amends Sec. 2725.1 &  
Adds Sec. 2725.2)**

The Nursing Practice Act authorizes a registered nurse to dispense drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a registered clinic. This bill would, in addition, authorize a registered nurse to dispense drugs or devices upon an order issued by a certified nurse-midwife, nurse practitioner, or physician assistant if the nurse is functioning within a specified clinic. The bill would also authorize a registered nurse to dispense hormonal contraceptives pursuant to specified standardized procedures, if the nurse is functioning within a licensed clinic.

## CHAPTER 16

### IMPORTANT TIME PERIODS ALLOTTED BY CALIFORNIA PHARMACY LAW

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***TIME PERIOD NOTICE TO THE STATE  
BOARD OF PHARMACY***

- A. Within how many days must the Board be notified of a change of pharmacy ownership?<sup>1</sup>     *Within 30 days*
- B. Within how many days must the Board be notified of a change of an address or name?<sup>2</sup>     *Within 30 days*
- C. Within how many days must the Board be notified of a change of the pharmacist-in-charge?<sup>3</sup>     *Within 30 days*
- D. Within how many days must the Board be notified of drug loss (by destruction or pilferage)?<sup>4</sup>     *Within 30 days  
(if controlled substance  
DEA notified immed.)*
- E. Within how many days must the Board be notified in the case of a bankruptcy, insolvency, or receivership?<sup>5</sup>     *To be Reported  
Immediately in  
Writing*
- F. Within how many days must the Board be notified regarding any change in the pharmacy permit?<sup>6</sup>     *Within 30 days*
- G. Within how many days must the Board be notified by the PIC if a licensed employee of the pharmacy is involved in the theft, diversion, or self-use of a drug or exhibits behavior representing an impairment that affects that persons ability to practice?<sup>7</sup>     *Within 14 days*

**TIME LIMIT REQUIREMENTS IN THE  
KEEPING OF PHARMACY RECORDS**

- |   |  |
|---|--|
| A. Community pharmacy prescription records. <sup>8</sup>  | <i>At least 3 yrs after last filling of Rx</i>                             |
| B. Hospital pharmacy prescription records. <sup>9</sup>   | <i>At least 7 yrs after last filling of Rx</i>                             |
| C. Clinic pharmacy prescription records. <sup>10</sup>  | <i>At least 3 yrs after last filling of Rx.</i>                            |
| D. Patient Medication Profile records. <sup>11</sup>  | <i>At least 1 yr. from date of last entry.</i>                             |
| E. Pharmacy technician compliance records. <sup>12</sup>  | <i>3 yrs from time of making.</i>  |
| F. Controlled substance inventory records. <sup>13</sup>  | <i>3 yrs from taking of inventory.</i>                                     |
| G. Certificates of C.E. Course Completion. <sup>14</sup>  | <i>4 yrs from date of course completion.</i>                               |
| H. DEA Form 222 order records. <sup>15</sup>  | <i>3 years</i>   |
| I. Self-Assessment of Pharmacy record. <sup>16</sup> (Includes self-assessments for both sterile & non-sterile compounding) | <i>3 yrs. Completed odd year prior to July 1<sup>st</sup> of odd year.</i> |
| J. Patient Medication Error Documentation Records. <sup>17</sup>  | <i>For at least 1 year</i>   |

**TIME OR OTHER REQUIREMENTS FOR SATISFYING  
VARIOUS PHARMACY-RELATED RESPONSIBILITIES**

- |  |  |
|--|--|
| <b>A. Pharmacist-Intern Hour Requirement.<sup>18</sup></b>   | <b><i>1500 hrs</i></b>   |
| <b>B. Continuing Education Hour Requirement.<sup>19</sup></b>  | <b><i>30 hrs for each<br/>2 yr license re-<br/>newal period.</i></b> |
| <b>C. Interim Period for a Temporary Pharmacist-In-Charge.<sup>20</sup></b>  | <b><i>Shall not exceed<br/>120 days.</i></b>                         |
| <b>D. Taking of a Controlled Substances Inventory.<sup>21</sup></b>  | <b><i>Every 2 years.</i></b>   |
| <b>E. Number of Days in Which a Prescription for a Schedule II Drug Must be Filled.<sup>22</sup></b>   | <b><i>Within 6 months of<br/>the date Rx was<br/>written.</i></b>    |
| <b>F. Number of Days in Which a Prescription for a Schedule II Drug Must be Filled if Written for a Terminally Ill Patient in a SNF &amp; Time limit for filling total Rx if Rx is partially filled at intervals.<sup>23</sup></b> | <b><i>Within 60 days of<br/>the date Rx was<br/>written.</i></b>     |
| <b>G. Time Period in which to Electronically send in info On Schedule II, III &amp; IV Rxs Per the CURES Program.<sup>24</sup></b>   | <b><i>Under CURES Pro-<br/>gram must be sent<br/>weekly.</i></b>     |
| <b>H. Schedule II Security Rx to be sent By Prescriber to Pharmacy Pursuant To an Emergency Oral Order by Prescriber.<sup>25</sup></b>   | <b><i>Within 7 days<br/>from date<br/>ordered</i></b>                |

- |  |   |
|--|---|
| <p><b>I. If No Security Rx for Sched. II drug Is sent by Prescriber Pursuant to an Emergency Oral Order – Time Period Notification to DEA .<sup>26</sup></b></p> | <p><i>Within 144 hrs. after 7 days of the emergency oral order in writing to DEA</i></p>                      |
| <p><b>J. Time Period a Schedule III, IV or V Prescription Must be Filled or Refilled before it is Void.<sup>27</sup></b></p>                                     | <p><i>Usually within 6 months from date written. Refills not to exceed 120 days.</i></p>                      |
| <p><b>K. Expiration Date for any Compounded Prescription.<sup>28</sup></b></p>   | <p><i>6 months or less ( if any ingredient expires before 6 mo.)</i></p>                                      |
| <p><b>L. Expiration Date for Extemporaneous Unit Dose Preparations.<sup>29</sup></b></p>   | <p><i>1 year or less if manufacturer's exp. date is less than 1 yr.</i></p>                                   |
| <p><b>M. Renewal Time Period on a Pharmacy Permit.<sup>30</sup></b></p>  | <p><i>Must be renewed yearly.</i></p>   |
| <p><b>N. Renewal Time Period on a Sterile Compounding License<sup>31</sup></b></p>   | <p><i>Must be renewed yearly.</i></p>   |
| <p><b>O. Temporary Permit Issued Upon Transfer Of Ownership.<sup>32</sup></b></p>  | <p><i>180 days</i></p>  |
| <p><b>P. Period one must Renew License to Continue to Practice Pharmacy.<sup>33</sup></b></p>  | <p><i>Every 2 years. If license not renewed within 3 years of expiration , it shall not be renewable.</i></p> |

- Q. Max. Amount Of Time A Pharmacist May Leave The Pharmacy And Leave Other Non-Pharmacists the Pharmacy.**<sup>34</sup> *No more than 30 min. for meal or other breaks.*
- R. Period of Time Rx Records must Be produced from an Off-Site Storage Facility when Requested.**<sup>35</sup> *Within 48 hours.*
- S. Period of Time PIC must do investigation & report once a medication error is discovered.**<sup>36</sup> *Within 48 hrs of discovery of error*
- T. Max. amount that may be charged as an administrative fee in addition to the cost of an Emergency Contraceptive agent. (No adm. fee may be charged if OTC on Plan B)**<sup>37</sup> *\$10*

***PHARMACY CLOSURE AND VOIDING OF THE LICENSE BY THE STATE BOARD OF PHARMACY***

- A. Notice Requirement by Board and Response to Notice by Licensee.**<sup>38</sup> *After notice licensee must respond within 10 days.*
- B. Upon Closure of a Pharmacy, a Transfer of Drugs Notice Must be Provided to the Board.**<sup>39</sup> *Within 10 days of the closure, and must be in writing.*
- C. Definition of a Pharmacy being "Closed-Down."**<sup>40</sup> *Pharmacy no longer engaged in activity it was licensed for, or not operating at least one day per week in a 120 day period.*



**REFERENCES TO CHAPTER 15**

1. Title 16, Calif. Code of Regs., Sec. 1709[a]
2. Calif. Bus. & Prof. Code, Sec. 4100[a]
3. Title 16, Calif. Code of Regs., Sec. 1709[a]
4. Title 16, Calif. Code of Regs., Sec. 1715.6 & 21 Code of Fed. Regs. (CFR), Sec. 1301.76[b]. This latter regulation requires that the DEA regional office be notified (should be immediate) and that a DEA Form 106 be filled-out and sent to the DEA regional office.
5. Title 16, Calif. Code of Regs., Sec. 1705
6. *Ibid.* at Sec. 1709[b]
7. Calif. Bus. & Prof. Code, Sec. 4104[c]
8. Title 16, Calif. Code of Regs., Sec. 1717[f] & Calif. Health & Safety Codes, Sec. 11179
9. Calif. Health & Safety Codes, Sec. 11159
10. Calif. Bus. & Prof. Codes, Sec. 4180[a][2]
11. Title 16, Calif. Code of Regs., Sec. 1707.1[a][2]
12. *Ibid.* at Sec. 1793.7[d]
13. *Ibid.* at Sec. 1718 & 21 Code of Fed. Regs. (CFR), Sec. 1304
14. Title 16, Calif. Code of Regs., Sec. 1732.5[b]
15. Code of Fed. Regs., Sec. 1305.17[c] states DEA 222 forms be kept for 2 years, but must follow Calif. law that requires keeping DEA 222 records for 3 years, Calif. Bus. & Prof. Code, Sec. 4333[a]
16. Title 16, Calif. Code of Regs., Secs. 1715[a][d] & 1735.2[j]
17. *Ibid.* at Sec. 1711[f]
18. *Ibid.* at Sec. 1728[a][1]
19. *Ibid.* at Sec. 1732.5[a]. The exceptions to this requirement are: 1) C.E. requirement does not apply to licensees during the first 2 years immediately following their graduation from an accredited pharmacy school, 2) In cases of proven emergency or hardship (See *Ibid.* at Sec. 1732.6), or 3) Where one has forfeited their license to practice pharmacy.
20. Title 16, Calif. Code of Regs., Sec. 1709.1[e]

21. 21 Code of Fed. Regs. (CFR), Sec. 1304 & Title 16, Calif. Code of Regs., Sec. 1718. A special inventory form is provided by the federal government every 2 years for the inventory taking of all controlled substances. This filled-out form must be kept at the pharmacy for 3 years and is subject to inspection by the state board inspectors.
22. Calif. Health & Safety Codes, Sec. 11166.
23. Title 16, Calif. Code of Regs., Sec. 1745[c][1]
24. Calif. Health & Safety Code, Sec. 11165[d]
25. *Ibid.* at Sec. 11167[c]
26. *Ibid.* at Sec. 11167[d]
27. *Ibid.* at Sec. 11200[a][b]
28. Title 16, Calif. Code of Regs., Sec. 1735.2[h]
29. U.S.P. Pharmacopeia/National Formulary, U.S.P. 24/ N.F. 19, 1999 Edition, pg. 2589-90
30. Calif. Bus. & Prof. Codes, Sec. 4110[a]
31. *Ibid.* at Sec. 4127.1[a]
32. *Ibid.* at Sec. 4110[b]
33. *Ibid.* at Secs. 4401 & 4402[a]
34. Title 16, Calif. Code of Regs. Sec. 1714.1[e]
35. *Ibid.* at Sec. 1707[b]
36. *Ibid.* at Sec. 1711[d]
37. Calif. Bus. & Prof. Code, Sec. 4052.3[c]
38. *Ibid.* at Sec. 4312[a]. If no response or written objection has been provided by the owner licensee within 10 days, the Board may void the pharmacy's license without a hearing.
39. *Ibid.* at Sec. 4312[b]
40. *Ibid.* at Sec. 4312[e]



## **CHAPTER 17**

### ***BEING PREPARED FOR A STATE BOARD OF PHARMACY INSPECTION***

During the course of operating a community pharmacy, the probability that you will be visited by a California Board of Pharmacy inspector to review your practice site will perhaps become more frequent than in years past. Most inspections today are precipitated by either a consumer or health care professional's complaint. Such complaints have increased over the last ten years.

Listed below are thirty eight (38) areas in which state board inspectors may pay special attention while conducting an inspection of a community pharmacy. Keep in mind that the following list may not represent a complete itemization of all points covered in an actual Board inspection, but hopefully should serve as a guide for the more common matters of concern. Your being prepared for such an inspection of the items listed should be an ongoing activity so that you will always be ready for the day the board inspector walks into your pharmacy.

In consideration of being prepared for a board inspection, you should be concerned:

1. That each prescription in your file system (manual or electronic) is complete with information required by law.
2. That you have the necessary equipment to prepare prescriptions and resource references to adequately handle pharmacy practice related issues.
3. That your pharmacy inventory is void of any outdated or damaged pharmaceutical products and that such inventory is kept clean.

4. That each patient who receives a prescription drug for the first time is at least verbally counseled on the storage, use, proper compliance, cautions, and important common severe adverse effects and interactions associated with the specific drug.
5. That each patient who comes in with a new prescription and you reasonably believe will return for refills or other prescription drugs, must have a patient medication profile on file at the pharmacy containing information pursuant to Section 1707.1 of Title 16, California Code of Regulations.
6. That if drugs are lent, borrowed, bought or sold between pharmacies, a record or log must be kept by each pharmacy involved in such transactions noting the prescription drug involved, the strength, the amount involved and the date of the transaction.
7. That the pharmacy permit is properly displayed in a conspicuous place within the pharmacy.
8. That no other person other than a pharmacist or pharmacist-intern take information over the phone from a prescriber's office pertaining to an order for a new prescription or an existing modified prescription.
9. That there only be one pharmacy technician (with the exception of a second technician working exclusively on inpatient drug orders) and no more than two pharmacist-interns if only one pharmacist is working in the prescription area of a community (retail) pharmacy. If there are two or more pharmacists, then the allotted pharmacy technician ratio may increase by two for each additional pharmacist on duty. Thus, two pharmacists may have a total of three pharmacy technicians working.



10. That a policy and procedure and/or job description regarding the duties and responsibilities of a pharmacy technician be available along with evaluations indicating that the pharmacy technician is performing his or her job according to the written job policy and procedure and/or job description.
11. That only a registered pharmacist have possession of a key that opens the pharmacy. However, such a key may be passed on in a sealed envelope or container to a non-pharmacist store manager for placement in a locked unit, to be held as such for the next pharmacist coming on duty.
12. That the proper information be recorded on the back of a transferred prescription by both the sending and the receiving pharmacies.
13. That prescriptions filled by the pharmacy and not picked-up by the patient should be returned to stock within a reasonable period of time (perhaps within 30 days or sooner) from the date of their being filled.
14. That an auxiliary label cautioning the patient that is taking a prescription drug that has central nervous system-suppressing capabilities, that the drug may cause "drowsiness" or "should not be taken while driving or drinking alcohol."
15. That upon the manufacturer's recall of a drug with a specific lot number, that drug shall be pulled from the shelves of the pharmacy immediately to prevent it from being dispensed pursuant to a prescription order.

16. That the following notice shall be posted in a conspicuous place within the pharmacy area:

*Notice to Consumers*

*At your request, this pharmacy shall provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.*

*Ask your pharmacist if a lower-cost generic drug is available to fill your prescription.*

*Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.*

*Before taking any medicine, talk to your pharmacist – be sure you know:*

- *What is the name of the medicine and what does it do?*
- *How and when do I take it – and for how long? What if I miss a dose?*
- *What are the possible side effects and what should I do if they occur?*
- *Will the new medicine work safely with other medicines and herbal supplements I am taking?*
- *What foods, drinks or activities should I avoid while taking this medicine?*

*Ask your pharmacist if you have additional questions.*

17. That there shall be a designated pharmacist-in-charge for each pharmacy operation, and the party designated as pharmacist-in-charge shall be registered with the Board of Pharmacy. Each time there is a change in the pharmacist-in-charge the Board must be notified of the change within 30 days.
18. That if the pharmacy engages in the compounding of sterile products, that it secure a separate license from the Board of Pharmacy for the purpose of compounding these products. Also, engaging in the compounding of sterile products requires that policies, procedures, and a quality assurance program be in place.

19. That the pharmacist initial all labels affixed to prescription containers indicating that they have checked the filling of the prescription by either a pharmacy technician or a pharmacist-intern.
20. That a once every two year inventory of all Schedule II, III, IV, and V drugs in stock be taken and such inventory records be made available during a Board of Pharmacy inspection.
21. That a one inch red "C" appear on all Schedule III, IV, or V controlled substance prescriptions filled and to be integrated into your nonscheduled prescription drug files, unless such prescription records are maintained in an electronic data base system.
22. That the refrigerator functions properly with temperatures for both cold and freezer storage within the proper U.S.P. ranges for drugs that must be refrigerated (2.2°C/36°F). Also, no food or other non-drug items are stored in the refrigerator that contains the drug products.
23. That the pharmacist is present in the pharmacy area during business hours, and if he or she steps outside the area, he or she must be within a reasonable eyes-view of this area while it remains open or in operation. The law presently allows the pharmacist to leave the prescription area for up to 30 minutes and leaving non-pharmacist personnel within the pharmacy. However, during this period of pharmacist absence, the personnel may only engage in non-discretionary tasks (this also includes the pharmacist-intern).
24. That the pharmacist-in-charge of each pharmacy shall complete a self-assessment of the pharmacy's compliance with federal and state laws. The assessment shall be performed before July 1<sup>st</sup> of every odd-numbered year, or within 30 days of a hiring of a new PIC.

25. That every prescription for a Scheduled II, III and IV controlled substance must be transmitted electronically to Atlantic Associates Inc. or as arranged by the Department of Justice at least every week in which the prescription was filled and dispensed.
26. That the sink within the pharmacy has cold and hot running water.
27. That the pharmacy is kept clean and the area where prescriptions are processed is uncluttered in order to reduce the potential for error.
28. That your pharmacy has in place a quality assurance program that documents medication errors attributable to the pharmacy's personnel in order to assess medication errors so that the pharmacy may take appropriate action to prevent recurrences. Policies and procedures must be created that address such matters as how medication errors are to be handled, investigated, reported, and training programs along with evaluation of the pharmacy staff will be instituted.
29. That all ephedrine-like products containing ephedrine, pseudoephedrine, and/or norpseudoephedrine, are limited for sale up to 3.6 grams of the ephedrine-like ingredient on a daily basis per customer, and are not to exceed 9 grams for that customer on a monthly basis. This federal law as a more stringent rule is to replace the present State's law that limits sales to 3 packages or 9 grams per over-the-counter transaction.
30. That under federal law any retailer involved in the sale of ephedrine-like products over-the-counter must be "self-certified;" must provide employee training regarding the nature, storage and sale of these products; must store in secure areas; must require patient photo-identification; maintain logbooks accounting for each

sale of these products; and must ensure that there is legitimate use among purchasers who are 18 years or older.

31. That it is unlawful for any retailer to sell over-the-counter betadine or povidone solution with iodine content in excess of 1% or if less where such containers are 8 ounces or more, or tincture of iodine that is 2% or less and where such containers are in excess of one ounce.
32. That all information pertaining to patients served by the pharmacy must be kept confidential, and all systems used to maintain that information are secure.
33. That the pharmacy has a policy in place if any employed pharmacist on staff based upon religious, moral or ethical beliefs refuses to fill a given class or classes of drugs or devices. Such a policy should state at a minimum alternative measures that the pharmacist or pharmacy will undertake to ensure that the patient is provided his or her drug or device without an unreasonable delay.
34. That if a pharmacy does not have a drug or device in stock pursuant to a prescription brought in by a patient, the pharmacy personnel will be expected to: a) order the drug for the patient, or b) promptly transfer the prescription to another pharmacy nearby that has the drug in stock and can fill and provide the prescription order to the patient in a timely manner, or c) locate a pharmacy that has the drug or device that is nearby and direct the patient to that pharmacy to have the prescription filled.
35. That a pharmacist-in-charge notify the Board of Pharmacy regarding any licensed employee of the pharmacy who admits to or exhibits any mental, chemical or physical impairment that affects his or her



ability to practice; and/or any licensed employee of the pharmacy who admits or is found to be involved in the theft, diversion, or self-use of dangerous drugs. Such inappropriate behavior by a licensed employee is to be reported to the board within 14 days once there is knowledge of such inappropriate behavior.

36. That a pharmacy does not exceed the administrative fee of \$10 above the cost of dispensing an emergency oral contraceptive pursuant to either the State's or a physician's directed protocol. And that no administrative fee be charged on the over-the-counter Plan B sale of the EC.
37. That only a pharmacist or pharmacist intern can check-in and sign-off on a drug order invoice for drugs delivered to the pharmacy from a drug wholesaler, manufacturer or distributor.

### 38. Required Policies and Procedures

Over the last ten to fifteen years, both federal and California laws have required that pharmacists create written policies and procedures on a number of pharmacy-related activities occurring within their community pharmacy practices. While some of these policy-procedure requirements may have already been stated above, this section is to remind the reader that his or her pharmacy must have the following written policies and procedures ready for inspection if that pharmacy engages in the activity described. Among those major written policies and procedures being required are the following:

- The job description duties, training and responsibilities of a pharmacy technician.
- Pharmacy technicians checking the pharmacy-related work (e.g. filling the medication orders for patients in acute hospitals) of other pharmacy technicians in the acute hospital setting.

- Description of the pharmacist's role in following protocols that extend his or her scope of practice.
- Participation in immunization programs.
- Provision of emergency oral contraceptives pursuant to a physician-directed or a statewide protocol.
- Where a pharmacist refuses to fill a prescription based upon religious, moral, or ethical concerns.
- The operations occurring in the pharmacy during the temporary absence of the pharmacist.
- Where a licensed employee is known to have at one time engaged in the theft or diversion of self-use prescription drugs there be policies and procedures stating the action to be taken if such a licensed employee subsequently engages in similar illegal activities causing them to be a danger to the public.
- The pharmacy's quality assurance program in the reporting of medication errors.
- Repackaging of prescription drugs for patients.
- The ordering, storing and dispensing of prescription drugs along with provision of other pharmacy services in a clinic environment overseen by a consulting pharmacist.
- The use, servicing, security, and accountability of a clinic's installing an automated drug delivery system.
- The use, servicing, security, and accountability of a community pharmacy's installment of an automated drug delivery system.
- Furnishing of prescription drugs to home health agencies and licensed hospices in sealed containers.
- The compounding of sterile products prepared in a community pharmacy setting.



## CHAPTER 18

### REVIEW QUESTIONS

This section is devoted to one hundred and seventy (170) multiple choice questions for review purposes. Following the questions is a discussion on the answers. Between the questions and the answers are answer sheets to record your responses. Set aside between two and three hours to take the test under simulated testing conditions. After you complete the test, then go on to review the answers.

Regarding the difficulty of these 170 questions, you will find that many are easy to respond to while an equal number require some careful thought and analysis. While many require that you be familiar with the law in this area, others will require that you apply the law along, in some cases, with common sense.

The following are some hints for taking this test and hopefully doing reasonably well:

1. You should probably read this book (Chapters 1 through 17) before taking the test to give you the necessary background you will need to score high. Also, you should probably read through your most current "California Pharmacy Law Text" in order to reinforce your understanding of the law.
2. Make sure you read each question carefully and thoroughly. Some of these questions have more than one right answer. What you need to be concerned with is to choose the very best answer.
3. While reading each question, make sure that you underline or circle key words or points in the question so that you do not get lost in understanding the question. Be careful of phrases like "*Which one of the following is not the correct response.*" This and other phrases like it should be underlined or circled.

4. Questions that have the choice - *“Is it or is it not a violation of the law?”* and *“Is it or is it not in the best interest of the patient?”* should be considered a two-prong response to be divided and each prong answered separately. Remember, questions containing these types of choices must be read very carefully, generally because the stem of the question or fact pattern will be long. Over the last several years the Board Exam has not been using this type of question since one can theoretically answer the question, *“whether or not it is in the best interest of the patient,”* with defensible answers that take into account both sides of the argument.
5. Do not add more facts to the stem of the question than are presented. If the creator of the question, for instance, tells you that it is a *“legitimate prescription,”* then accept it as a legitimate prescription - *Don’t try to fight the question.*
6. The California Pharmacy Practice Standards and Jurisprudence portion of the examination, which has approximately 90 multiple choice questions, presents a number of pharmacy law-related questions that apply to practice, along with clinical and pharmacy business associated questions. As noted by the Board, the following is a general breakdown of the category of questions that may be asked on the *California Pharmacy Practice Standards and Jurisprudence Examination (The following information is directly from the Board of Pharmacy’s Website):*

## **I. Patient Medications (25 Items)**

### **A. Organize and Evaluate Information**

1. Obtain information from the patient/patient's representative for patient profile (diagnosis or desired therapeutic outcome, allergies, adverse reactions, medical history, etc.)
2. Obtain information from prescriber and/or health care professionals for patient profile (diagnosis or desired therapeutic outcome, allergies, adverse reactions, medical history, etc.)



3. Assess prescription/medication order for completeness, correctness, authenticity, and legality
4. Assess prescription/medication order for appropriateness (e.g., drug selection, dosage, drug interactions, dosage form, delivery system)
5. Evaluate the medical record/patient profile for any or all of the following: disease states, clinical condition, medication use, allergies, adverse reactions, disabilities, medical/surgical therapies, laboratory findings, physical assessments and/or diagnostic tests
6. Evaluate the pharmaceutical information needs of the patient/patient's representative
7. Assess prescription/medication order for insurance coverage

## **B. Dispense Medications**

1. Enter prescription information into patient profile
2. Select specific product(s) to be dispensed for a prescription/medication order
3. Document preparation of medication in various dosage forms (e.g., compounded, unit dose)
4. Document preparation of controlled substances for dispensing
5. Verify label(s) for prescription containers
6. Select auxiliary label(s) for container(s)
7. Perform the final check of the medication prior to dispensing
8. Use automated dispensing equipment (e.g., Pyxis, Omnicell, AccuDose, ScriptPro)
9. Prepare finished dosage forms for dispensing (e.g., measure, count, reconstitute, compound, repackage, unit dose)

## **II. Patient Outcomes (30 Items)**

### **A. Determine a Course of Action**

1. Determine desired therapeutic outcomes
2. Develop a therapeutic regimen for prescription medications (e.g., recommend alteration of prescribed drug regimen; select drug if necessary)
3. Assess changes in health status (e.g., onset of new disease states, changes in clinical condition)
4. Recommend/order necessary monitoring and screening procedures (e.g., blood pressure, glucose levels, drug levels)
5. Document monitoring and therapeutic management activities
6. Manage drug therapy according to protocols
7. Resolve problems that arise with patient's therapy (e.g., ADRs, drug interactions)

## **B. Educate Patients and Health Care Professionals**

1. Assess the patient's understanding of the disease and treatment
2. Counsel patient/patient's representative regarding prescription medication therapy and devices
3. Counsel patient/patient's representative regarding nonprescription medication (OTC)
4. Counsel patient/patient's representative regarding herbal/complementary therapies
5. Counsel patient/patient's representative regarding non-drug therapy
6. Counsel patient/patient's representative regarding self-monitoring of therapy (e.g., devices, symptoms)
7. Verify the patient's/patient representative's understanding of the information presented
8. Educate health care professionals (e.g., physicians, nurses, medical residents/fellows, other health care providers/students, precepting intern pharmacists)
9. Communicate results of monitoring to patient/patient's representative, prescriber and/or other health care professionals
10. Respond to consumer inquiries (e.g., internet searches, media information, FDA patient safety alerts, radio/television commercials)
11. Provide supplemental information, as indicated (e.g., medication guides, computer generated information, videos)

## **III. Pharmacy Operations (20 Items)**

### **A. Procure Pharmaceuticals, Devices and Supplies, and Control Inventory**

1. Place orders for pharmaceuticals, durable medical equipment, devices and supplies, including expediting of emergency orders
2. Maintain a record-keeping system of items purchased/received/returned in compliance with legal requirements (e.g., dangerous drugs, devices, supplies)
3. Maintain a record of controlled substances ordered, received, stored and removed from inventory
4. Dispose of expired or recalled pharmaceuticals, durable medical equipment, devices, supplies and document actions taken
5. Communicate changes in product availability (e.g., formulary changes, recalls, shortages) to pharmacy staff, patient/patient's representative, physicians and other health care professionals
6. Maintain policies and procedures to prevent theft and/or drug diversion

**B. Perform Quality Assurance/Improvement**

1. Assess pharmacist and/or pharmacy technician competence
2. Ensure the accuracy of medication administration
3. Participate in a system for medication error prevention, assessment, and reporting (e.g., root cause analysis, National Patient Safety Goals, medication error reduction program)
4. Participate in a system by which adverse drug reactions are documented, analyzed, evaluated and reported

**C. Manage Operations, Human Resources and Information Systems**

1. Monitor the practice site and/or service area for compliance with federal, state and local laws, regulations and professional standards/guidelines
2. Supervise the work of pharmacy staff
3. Ensure the availability, control, and confidentiality of patient and prescription information (e.g., patient profiles, medication administration records)

**D. Manage Medication Use System**

1. Maintain a formulary system
2. Apply therapeutic interchange
3. Conduct medication use evaluations

**TOTAL: 90 QUESTIONS, THAT INCLUDES 15  
NONSCORED, PRETEST ITEMS**

7. While you must know the law to answer these questions, recognize the fact that most all laws are based upon common sense and ethical principles. Therefore, if you don't know the answer to a particular question, allow your common sense to guide you - and you will find that you can still get the question right.

***GOOD LUCK AND I WISH YOU HIGH SCORES***

1. When nonscheduled prescription drugs are lent, borrowed, sold or bought between pharmacies, the responsibility of each pharmacist and pharmacy is as follows:
  - a. Each pharmacy must keep a log of the prescription drug lent or borrowed. No record or log need be kept if the drug is bought or sold.
  - b. Only the lending or selling pharmacy must keep a log of the prescription drug transferred.
  - c. Only the borrowing or buying pharmacy must keep a log of the prescription drug transferred to it.
  - d. Both pharmacies must keep a log of the transfer whether it is lent, sold, borrowed or bought.
  - e. Neither pharmacy must keep a log if a drug is transferred between the pharmacies.
  
2. When a Schedule II controlled substance is transferred between pharmacies, which one of the following is correct?
  - a. A special F.D.A. transfer form is required.
  - b. A special D.E.A. transfer form is required.
  - c. A special Department of Consumer Affairs form is required.
  - d. A special Board of Pharmacy form is required.
  - e. No form is required.
  
3. Which one of the following matters must be reported to the California State Board of Pharmacy immediately (usually within 72 hours)?
  - a. Change in a pharmacist licensee's residential address.
  - b. Change in the ownership of a pharmacy.
  - c. Drug robbery or burglary where controlled substances have been taken.
  - d. A pending bankruptcy, receivership or insolvency of one's pharmacy business.
  - e. A fire that destroys 80% of your prescription drug stock, including controlled substance drugs.

4. Mrs. Jones calls you to fill and deliver her prescription for *Haldol 5mg* tablets (5 refills remaining). She asks that you deliver the medication to her home and leave it with her 15 year old son, Timmy, since she will be at work. When the delivery person for the pharmacy takes the *Haldol* prescription to Mrs. Jones' home, Mrs. Jones' son (Timmy) is not there, nor is anyone else. The delivery person decides to go to Mrs. Jones' next door neighbor, Mr. Marshall, to hold the medication for Mrs. Jones until she gets home. Accordingly, what the delivery person did on behalf of the pharmacy is:
- A violation of the law, but in the best interest of Mrs. Jones.
  - A violation of the law, and not in the best interest of Mrs. Jones.
  - Not a violation of the law, and in the best interest of Mrs. Jones.
  - Not a violation of the law, but not in the best interest of Mrs. Jones.
5. Which one of the following statements is incorrect regarding the pharmacist's responsibilities in giving prescription drug prices to a patient who requests such prices before having their prescription filled?
- The pharmacist must provide the patient with a price for a controlled substance prescription when the request is telephoned in by the patient.
  - The pharmacist shall give the current retail price for any drug sold at that pharmacy upon the walk-in request of the consumer.
  - If there is a request for the prescription prices of more than 5 drugs, the pharmacist may charge a reasonable fee for each prescription price quote as long as the requester is informed that they will be charged such a fee.
  - A pharmacy shall not be required to respond with price quotes to more than 3 requests for 5 or more prescription drugs from any one person or entity in a six-month period.
  - The pharmacist is not obligated to provide drug prices if the price request is from an out-of state requester.



6. Which one of the following statements is correct regarding the drug *ketamine*?
  - a. *Ketamine* is both federally and in California classified as a Schedule IV controlled substance.
  - b. *Ketamine* in California is classified as a Schedule II controlled substance, and federally it is classified as a Schedule IV controlled substance.
  - c. *Ketamine* is both federally and in California classified as a Schedule III controlled substance.**
  - d. *Ketamine* in California is classified as a Schedule IV controlled substance and federally it is classified as a Schedule III controlled substance.
  - e. *Ketamine* in California, and also federally, is not classified as a controlled substance.
  
7. Four physicians and a pharmacist wish to buy a community pharmacy in California. If they desire to hold the pharmacy as a corporation, what percentage of ownership may the four physicians and one pharmacist have in that pharmacy corporation?
  - a. Each may own 20% of the stock in that pharmacy corporation.
  - b. The four physicians may only hold up to 50% of the corporation shares and the pharmacist may hold the other 50% of the corporation's shares.
  - c. The four physicians each may only hold 2 1/2 shares and the pharmacist may own up to 90% of the corporation shares.
  - d. The four physicians collectively may only hold up to 10% of the corporation's shares (those shares may be held in any proportion desired by the four physicians) and the pharmacist may own up to 90% of the shares in the corporation.**
  - e. The physicians may not own any shares in the pharmacy corporation.

8. Which one of the following licensed health care providers may not prescribe drugs?
- ☒ a. Doctor of Chiropractic Medicine
  - b. Doctor of Osteopathic Medicine
  - c. Podiatrist
  - d. Veterinarian
  - e. Psychiatrist
9. A community pharmacy must keep a prescription record on a patient for what period of time after the last dispensing of the drug?
- a. 2 years.
  - ☒ b. 3 years.
  - c. 5 years.
  - d. 7 years.
  - e. 9 years.
10. A patient who has been a customer of yours for the last 5 years recently went to his dentist and had a tooth extracted. At the time of the extraction he did not feel much pain. Now, besides complaining of the pain, he also tells you he cannot sleep. He asks you for one *Tylenol with Codeine 1 gr.* tablet and one *Dalmane 30 mg* capsule and to call his dentist in the morning for an extended prescription for these medications. The patient has never had a prescription for these medications in the past, at least to your knowledge. You decide to provide him with one tablet and capsule of each because you know his dentist real well. As a result, this would most likely be:
- a. A violation of the law, but in the best interest of the patient.
  - ☒ b. A violation of the law, and not in the best interest of the patient.
  - c. Not a violation of the law, and in the best interest of the patient.
  - d. Not a violation of the law, but not in the best interest of the patient.

11. Mrs. Jones comes into your pharmacy (a for-profit business operation) with a prescription for 30 *Augmentin* 250 mg tablets to be taken one every 8 hours until finished. You just filled and dispensed a prescription for the same medication an hour earlier and as a result you do not have anymore of the drug in stock. You call your friend Joe who is the pharmacist-in-charge at the county clinic pharmacy across the street from your pharmacy. Joe agrees to sell you 30 tablets of *Augmentin* at his acquisition price of \$0.30 per tablet (based on the clinic's non-profit status). You, however, must purchase the same tablets from your wholesaler at about \$2.00 each. After paying for and picking-up the *Augmentin* tablets, you dispense the medication to Mrs. Jones and charge her according to your usual wholesale cost; thus charging her \$82.50 for this prescription. On the basis of procuring the *Augmentin* at the price you did and selling it to Mrs. Jones at your usual price, this would be considered:
- a. A violation of the law, but in the best interest of the patient.
  - b. A violation of the law, and not in the best interest of the patient.
  - c. Not a violation of the law, and in the best interest of the patient.
  - d. Not a violation of the law, but not in the best interest of the patient.
12. The minimum area for operating a community pharmacy is:
- a. 200 sq. ft. (including storage area or bathroom facilities).
  - b. 240 sq. ft. (including storage area and bathroom facilities).
  - c. 240 sq. ft. (not including storage area and bathroom facilities).
  - d. 280 sq. ft. (including storage area and bathroom facilities).
  - e. The area must be a reasonable area sufficient to accommodate for the safe and efficient performance of pharmacy-related activities.
13. Secobarbital suppositories are classified as a:
- a. Schedule I controlled substance.
  - b. Schedule II controlled substance.
  - c. Schedule III controlled substance.
  - d. Schedule IV controlled substance.
  - e. Schedule V controlled substance.

14. Southern California is hit by an earthquake of a 8.5 magnitude. The Governor and President have declared California in a "state of emergency." Your pharmacy happens to be one of the few standing in the area. Mrs. Smith who suffered a fracture in her right arm above the elbow two weeks prior to the earthquake is completely out of her *Tylenol with Codeine 1 gr.* prescription which she received at another pharmacy 5 miles away about two weeks ago. She comes to your pharmacy to see if you will fill her prescription. She also tells you that she traumatized her right arm during the earthquake and needs the pain medication badly. It is impossible to reach both the other pharmacy and her physician, so you provide her with approximately a 72 hour supply which you put-up in a container and label as though it were a newly issued prescription. You record on a log the medication you provided Mrs. Smith, the strength, the number given, the name and address of the patient, the date given, the information about the pharmacy it was originally filled at including last time it was filled, the name of the prescribing physician and where he or she can be contacted, and the reason for providing the emergency supply. What you have done is considered to be:
- A violation of the law, but in the best interest of the patient.
  - A violation of the law, and not in the best interest of the patient.
  - Not a violation of the law, and in the best interest of the patient.
  - Not a violation of the law, but not in the best interest of the patient.
15. Which one of the following items is not required by law on a prescription after it is filled and before it is filed away?
- The date filled.
  - The price of the prescription.
  - Initials of the pharmacist if the prescription was filled by a pharmacy technician.
  - Prescription identification number required for having access to the prescription.
  - Manufacturer or trade name if a generic drug substitution is made.

16. Concerning the sale of hypodermic needles and syringes, which one of the following is the most correct answer?
- a. Anytime hypodermic needles and/or syringes are sold over-the-counter, the *State Hypodermic Needle and Syringe Record Book* must be filled-in and signed.
  - b. Hypodermic needles and syringes may only be sold over-the-counter for any patients purchasing them for the injection of insulin, adrenalin, and Vitamin B-12 injections.
  - c. If a California county or city determines it wishes to set-up a program where it registers pharmacies within that county or city to give out syringes and needles OTC to prevent the spread of AIDs or Hepatitis C, the person picking up those needles for either of those purposes must show identification and sign-in on the *State Hypodermic Needle and Syringe Record Book*.
  - d. California no longer requires the use the *State Hypodermic Needle and Syringe Record Book* primarily because patients who need syringes and needles for the injection of insulin or epinephrine may only receive those syringes and needles pursuant to a prescription written by a prescriber.
17. Which one of the following is incorrect regarding the time period that each of the following records must be kept in a California pharmacy?
- a. The patient medication profile must be kept for at least one year after the last date of entry.
  - b. A medication error record report must be kept for 3 years.
  - c. A federal drug inventory for controlled substances must be kept for 3 years.
  - d. A DEA Form 222 order record must be kept for at least 3 years.
  - e. A pharmacy self-assessment record completed by the pharmacist-in-charge must be kept for 3 years.



18. Pharmacy "A" arranges with Pharmacy "B" to prepare prescriptions (fill the prescription with drugs from Pharmacy "A's" stock) brought into Pharmacy "B" by patients, and then deliver them back to Pharmacy "B" so that the pharmacist only has to counsel the patients about their medications and do DURs and not have to physically fill the prescriptions. In consideration of this arrangement, which one of the following statements is most correct?
- a. It is illegal for Pharmacy "A" to fill the prescriptions for patients who deliver their prescriptions to Pharmacy "B."
  - b. It is legal for Pharmacy "A" to fill the prescriptions for patients who deliver their prescriptions to Pharmacy "B" as long as Pharmacy "A" uses the labels from Pharmacy "B"
  - c. It is legal for Pharmacy "A" to fill the prescriptions for patients who deliver their prescriptions to Pharmacy "B" as long as Pharmacy "A" uses its own labels on the prescriptions it fills for Pharmacy "B"**
  - d. Pharmacy "A" must use drug supplies from Pharmacy "B" in order to fill prescriptions brought into Pharmacy "B" and will be dispensed by Pharmacy "B."
  - e. Pharmacy "A" may fill prescriptions brought into Pharmacy "B" to be dispensed to patients in Pharmacy "B" as long as they are non-scheduled medications only.
19. Which one of the following statements is incorrect regarding a physician's order for a controlled substance?
- a. A physician cannot write a scheduled controlled substance prescription for himself or herself.
  - b. A physician cannot post-date a prescription for a scheduled controlled substance.
  - c. A physician cannot write a scheduled controlled substance prescription for a member of his or her immediate family.**
  - d. A physician cannot ante-date a prescription for a scheduled controlled substance.
  - e. A physician cannot write a prescription order for a controlled substance to treat for addiction only, unless the party addicted is registered with a government or other authorized agency licensed to treat narcotic addicts and the physician is authorized to participate in such a treatment program.

20. While Mrs. Smith is in the hospital being treated for a possible estrogen deficiency. Dr. Wilcox wishes to provide her with injections of an estrogenic agent. When the pharmacy gets the order, the pharmacist notes that Dr. Wilcox in addition to the estrogenic drug request, states that he does not want Mrs. Smith to receive any written or verbal information about the estrogenic drug product from the pharmacy, because he feels it may scare her (the manufacturer's information to the patient contains stated risks such as the possible development of possible breast or uterine cancer). If you comply with Dr. Wilcox's written request not to provide the patient with any written information about the estrogenic drug, this would be considered:
- a. A violation of the law, but in the best interest of the patient.
  - b. A violation of the law, but not in the best interest of the patient.
  - c. Not a violation of the law, and in the best interest of the patient.
  - d. Not a violation of the law, but not in the best interest of the patient.
21. Which one of the following statements is incorrect regarding the transferring of prescriptions between pharmacies?
- a. A pharmacy clerk can transfer information regarding a prescription to be filled at a pharmacy, but only the pharmacist at the receiving pharmacy may record the information being transmitted from the sending pharmacy by the clerk.
  - b. The receiving pharmacy must take all the remaining refills left on the prescription being transferred, while the sending pharmacy must cancel the prescription from being refilled once transferred.
  - c. Nonscheduled drug prescriptions may be transferred to different pharmacies as many times as there are refills.
  - d. Schedule III, IV, and V controlled substance prescriptions with refills may be transferred to another pharmacy only one time.
  - e. The receiving pharmacy for a transferred prescription with refills must record, among other things, the date the prescription was originally written, and the date of the last refill.

22. Which one of the following statements is most correct regarding the CURES Program and the reporting to a central government data base information about the filling of controlled substance prescriptions by pharmacies?
- Only Schedule II prescriptions that are filled must be reported.
  - Only Schedule II and III prescriptions that are filled must be reported.
  - Only Schedule II, III, and IV prescriptions that are filled must be reported.
  - All Scheduled controlled substance prescriptions that are filled must be reported.
  - No longer do Schedule II prescriptions have to be reported.
23. A patient brings into your pharmacy on January 12, 20xy a legitimate prescription on a special security prescription form for *Percodan* tablets # 20. When is approximately the last date you can fill this prescription if it was written and dated by the prescriber on January 10, 20xy?
- By January 17, 20xy.
  - By January 23, 20xy.
  - By January 21, 20xy.
  - By March 12, 20xy
  - By July 10, 20xy
24. What must the missing number be in the following physician's federal DEA registration number in order that the 7 digit sequence will be consistent with the DEA's standard for legitimizing such numbers?

AR 63 ? 5877


- 1
- 2
- 3
- 4
- 5

25. A patient comes into your pharmacy on a Friday evening with an empty vial, originally filled in your pharmacy, for 50 *Tylenol with Codeine 1 gr. tablets*. The patient has been getting this medication from an orthopedic surgeon for the last 2 years for a severe chronic back injury. His doctor is out of town until Monday and because the patient is in a great deal of pain, you decide to extend to him a 3 day supply of the drug. As a result, this is:
- A violation of the law, but in the best interest of the patient.
  - A violation of the law, and not in the best interest of the patient.
  - Not a violation of the law, and in the best interest of the patient.
  - Not a violation of the law, but not in the best interest of the patient.
26. A pharmacy technician can do all of the following tasks under the supervision of a pharmacist, except which one of the following?
- Mix pharmaceuticals.
  - Repackage medications.
  - Answer a question from a prescriber, after researching it, about the clinical effects of a drug as long as the pharmacy technician states the source from which the statement is made.
  - Count the tablets required by a prescription and place them into a container.
  - Prepare prescriptions that are for controlled substances.
27. Which one of the following drugs was taken off the Schedule II controlled substance drug list in California, and no longer is considered a controlled substance?
- Methaqualone
  - Phenobarbital
  - Chorionic gonadotropin (HCG)
  - Apomorphine
  - Soma (carisoprodol)

28. If a prescription is filled within a clinic pharmacy, the filed prescription record must be kept for how many years from the date it was last filled?
- a. Two years.
  - b. Three years.
  - c. Five years.
  - d. Seven years.
  - e. Ten years.
29. A medication profile must be kept as a pharmacy record for what period of time from the last date a medication was filled?
- a. One year.
  - b. Two years.
  - c. Three years.
  - d. Five years.
  - e. Seven years.
30. Which one of the following statements is true regarding the "Patient Consultation Regulation" in California?
- a. The California regulation reads in pertinent part that "The pharmacist must offer to orally consult with the patient."
  - b. A pharmacist may counsel a patient about their new prescription drug by providing a written communication. This "written" substitution for an oral consultation is allowed based on the law.
  - c. In that the law states that a pharmacist must orally consult with the patient about their new prescription medications, a pharmacist-intern is therefore not allowed to consult with the patient about their new prescriptions.
  - d. For a patient who is being discharged with new prescriptions from the hospital, someone other than the pharmacist may provide the consultation.
  - e. When new prescription medications are delivered to a patient at home by the pharmacy, the pharmacist must call the patient to provide an oral consultation on their medications with that patient.



31. Out-of-state prescriptions for nonscheduled controlled substances which may be validly filled in California may not be refilled, even if the out-of-state prescriber has authorized additional refills on the original prescription.
  - a. True
  - b. False
  
32. A patient comes into your pharmacy from out-of-state with an empty labeled prescription vial that contained Digoxin 0.25 mg one daily medication. The patient has been on the medication for the last 10 years, but forgot to get it refilled before she left home in Texas for her vacation in California. You are unable to reach her physician, and she has no more refills left on this prescription according to the Texas pharmacy where she gets it filled - so you decide to provide her with 3 tablets (72 hours worth) in her original vial until you can reach her physician on Monday. This is:
  - a. A violation of the law, but in the best interest of the patient.
  - b. A violation of the law, and not in the best interest of the patient.
  - c. Not a violation of the law, and in the best interest of the patient.
  - d. Not a violation of the law, but not in the best interest of the patient.
  
33. Regarding the present law as to the number of pharmacist interns and pharmacy technicians you may have at any given time during the time the community pharmacy is opened, if you have two pharmacists on duty, then which one of the following represents the correct ratio of each (the pharmacist intern and the pharmacy technician) that you may have at the same time the two pharmacists are on duty?
  - a. One pharmacist intern and two pharmacy technicians.
  - b. One pharmacist intern and three pharmacy technicians.
  - c. Two pharmacist interns and three pharmacy technicians.
  - d. Three pharmacist interns and three pharmacy technicians.
  - e. Four pharmacist interns and three pharmacy technicians.

- 34. Human Chorionic Gonadotropin (HCG) is:**
- a.    **Classed as a Schedule II controlled substance.**
  -  **Classed as a Schedule III controlled substance.**
  - c.    **Classed as a Schedule IV controlled substance.**
  - d.    **Classed as a Schedule V controlled substance.**
  - e.    **Not classed as a controlled substance.**
- 35. Which one of the following consultation items listed below is not mandatory whereby you may use discretion as to whether or not the patient needs to be consulted on that information.**
- a.    **Directions for use.**
  - b.    **The importance of compliance with the directions.**
  - c.    **Significant or common severe side effects.**
  - d.    **Directions for storage.**
  - e.    **What to do in case of a missed dose.**
- 36. After a pharmacy license has been voided or where a pharmacy owner notifies the state board of pharmacy of the intent to remain closed, within how many days after such notification must all drugs be arranged for to be transferred to another licensee (pharmacy or wholesaler) and the board so informed of the transfer in writing?**
- a.    **Immediately.**
  - b.    **Within 10 days.**
  - c.    **Within 30 days.**
  - d.    **Within 60 days.**
  - e.    **Within 90 days.**

37. If a pharmaceutical manufacturer does not place an expiration date on its prescription drug product:
  - a. The drug is considered to have been expired and cannot be dispensed pursuant to a prescription order.
  - b. You may use the expiration date from a comparable product from another manufacturer who has placed an expiration date on their product.
  - c. You may use a 60 day expiration date from the date the product is dispensed.
  - d. You may use a 6 month expiration date from the date the product is dispensed.
  - e. You may use a one year expiration date from the date the product is dispensed.
  
38. Dr. Edwards' office faxes a prescription for *Vasotec* 10 mg to be taken once daily, # 100 for Mrs. Jones. The facsimile that comes to your pharmacy through your fax machine is complete with all the required information. Concerning the transmitted facsimile for the *Vasotec* prescription, which one of the following statements is correct?
  - a. Dr. Edwards' faxed prescription for the *Vasotec* cannot be honored under any circumstances.
  - b. Dr. Edwards' faxed prescription for the *Vasotec* may be honored, however, you must rewrite the prescription on your own prescription blanks - but you need not call Dr. Edwards for a verification of the prescription.
  - c. Dr. Edwards' faxed prescription for the *Vasotec* may be honored; however, you must rewrite the prescription on your own prescription blanks and call Dr. Edwards to verify the prescription.
  - d. Dr. Edwards' faxed prescription for the *Vasotec* may be honored without rewriting it. Also, Dr. Edwards does not have to be contacted to verify the prescription, as long as you have reasonable evidence that the prescription came from the prescriber (or an authorized designee of the prescriber) and not from the patient.
  - e. In order for Mrs. Jones to receive the *Vasotec* from your pharmacy, she must bring in an original copy of the prescription that was faxed. The faxed copy is then torn up and the original prescription is placed in your files.

39. A patient comes into your pharmacy with a prescription for a 60 gram amount of *Triamcinolone 0.1% Cream*. You are totally out of the cream but have a 60 gram size of *Triamcinolone 0.1% Ointment*. Without calling the patient's physician, you tell the patient that you do not have the cream in stock, and tell her that you are providing her with the ointment which is the same strength and price as the cream, and is the same drug in an ointment instead of a cream. You then dispense the ointment to the patient and counsel her on the use of the medication according to the requirements under the "Consultation Regulation." Is this drug substitution in compliance with California law?
- Yes
  - No
40. A nonscheduled drug prescription for a patient comes to you in your pharmacy over the internet. Regarding the filling of this prescription, which one of the following statements is the most correct?
- Any prescription that is sent over the internet cannot be filled.
  - An internet generated prescription may only be filled if it is sent from the prescriber with his or her initials, and is not sent by an employee or designee of the prescriber using their initials.
  - An internet generated prescription may be filled if its sent by an employee or designee of the prescriber as long as it indicates who sent the prescription.
  - An internet generated prescription in order to be filled must bear the name or initials of the person sending it whether the prescriber or his or her designee, and assurances that the medication was ordered as the result of a good faith examination on the part of the prescriber.
- 41 Any thermometer containing mercury required by a patient must be sold in California pursuant to a prescriber's prescription.
- True
  - False

42. In the execution of a DEA Form 222 (used for Schedule II controlled substance transfers and the forms come in a triplicate set);
- The first copy goes to the DEA, the second copy is retained by the pharmacy, and the third copy is retained by the wholesaler.
  - The first copy is retained by the wholesaler, the second copy is sent to the DEA, and the third copy is retained by the pharmacy.
  - The first copy is retained by the pharmacy, the second copy is retained by the wholesaler, and the third copy goes to the DEA.
  - The first copy is retained by the pharmacy, the second copy is sent to the DEA, and the third copy is retained by the wholesaler.
  - The first and second copy are retained by the wholesaler, and the third copy goes to the DEA.
43. A pharmacy clerk working in a community pharmacy may take a prescription refill over the phone from a customer who calls in the prescription refill number?
- True
  - False
44. Only a pharmacist may own a pharmacy in California?
- True
  - False
45. In order for a patient to allow a pharmacy that networks through an electronic file or computer system to transfer prescription information about a patient (such as in a chain pharmacy operation), that patient must sign a waiver allowing the pharmacy to transfer such information?
- True
  - False



46. Mrs. Smith had her original prescription for *Tylenol with Codeine 1 gr.* ( # 30 with directions of "one tablet every 4 hours as needed for pain") filled at your pharmacy on January 13, 20xy. She presently has 5 refills remaining. Assuming, that about a month later on February 10, 20xy she wishes to go to another pharmacy across town to get a refill, and intends to get her remaining 4 refills on a monthly basis thereafter. Which statement is incorrect regarding how this particular prescription is to be handled?
- Mrs. Smith may get the refill at the second pharmacy.
  - If Mrs. Smith were to go to a third pharmacy (completely different from the first two) in March 20xy, she may not get a refill from the third pharmacy (even though refills remain) without her physician being contacted and approving the refill.
  - Mrs. Smith may get her refill at the second pharmacy. Further, Mrs. Smith may get a subsequent refill (a second refill) on March 20xy by returning to her original pharmacy (the first pharmacy) and using the information on the original prescription written without the pharmacist either calling the second pharmacy or the prescriber for approval.
  - If the prescription is refilled for the first time on February 13, 20xy at the second pharmacy, the pharmacist must record on the back of the prescription after filling: a) date the prescription was first filled and written; b) date of last refill; c) DEA of sending pharmacy; d) date filled; e) name and address of the sending pharmacy; and f) name of pharmacist transmitting the prescription information.
47. Mrs. Smith in Question 46 above goes to the second pharmacy to receive her remaining refills - one refill each month on the 10<sup>th</sup> of each subsequent month in the schedule shown below:
- 1<sup>st</sup> refill — February 10, 20xy
  - 2<sup>nd</sup> refill — March 10, 20xy
  - 3<sup>rd</sup> refill — April 10, 20xy
  - 4<sup>th</sup> refill — May 10, 20xy
  - 5<sup>th</sup> refill — June 10, 20xy
- All of her 5 refills for the 30 *Tylenol w/Codeine ½ gr* are refilled by the second pharmacy on the dates indicated. As a result has the second pharmacy violated any State or federal laws?
- Yes
  - No

48. If a pharmacist is registered in both California and Nevada and while working in Nevada is charged and convicted of a pharmacy related misdemeanor, this will in no way cause the California Board of Pharmacy to act on his California license (with the possibility of either revoking or suspending it) since this misdemeanor only occurred in Nevada.
- True
  - False
49. Every patient who walks into your pharmacy with a new prescription must have a patient medication profile created?
- True
  - False
50. Concerning the filling of a security prescription for Scheduled controlled substances, if the physician writes for more than one controlled substance, he or she may write for multiple controlled substance drugs on a prescription if the security form has line divisions on it with quantity boxes for each line item, and there is a printed statement, usually at the lower portion of the prescription that states, "*This prescription is void if the number of drugs prescribed is not noted.*"
- True
  - False
51. Mrs. Klein has a new prescription for 100 *Dalmane* 30 mg. Capsules with 5 refills (*Dalmane* is a Schedule IV sedative/sleep medication) to be taken at "One capsule at bedtime for sleep." Based on California pharmacy law, how many times may you refill Mrs. Klein's prescription for this medication within a 6 month period before having to call her physician to approve her continuing on the *Dalmane*?
- One time.
  - Three times.
  - Four times.
  - Five times.
  - You may not refill the prescription without first calling her physician and receiving his or her authorization to refill.

52. A physician's prescription for Mrs. Smith comes to you on a preprinted, multi-drug prescription blank from the doctor's office. Contained on this preprinted, multi-drug prescription blank are eight (8) type-set, drugs, all of which are nonscheduled drugs. The prescription for Mrs. Smith has three (3) of these prescription drugs checked-off (an oral antibiotic, an oral antihistamine, and a prescription cough syrup [not containing codeine]). Upon receiving such a prescription, which one of the following statements is the most consistent with California pharmacy law?

- a. The prescriptions for the three (3) drugs may be filled as is without the addition of any further information, and without calling the physician for validation.
- b. The prescriptions for the three (3) drugs may be filled as is without the addition of any further information; however, the physician must be called for validating the 3 drugs written for.
- c. The prescriptions for the three (3) drugs may be filled as is as long as the physician has indicated on the prescription blank the number of nonscheduled prescription drugs he or she has prescribed, and the physician is required to be called to validate what he or she has written for.
- d. The prescriptions for the three (3) drugs may be filled as is as long as the physician has indicated on the prescription blank the number of nonscheduled prescription drugs he or she has prescribed, and it is not necessary that the physician be contacted to validate what has been written for.
- e. The entire prescription is void since only one nonscheduled drug can be ordered on this type of prescription form to be valid.

53. A pharmacist can advertise that they are a compounding pharmacy, but they cannot advertise that they do specialized compounded products such as certain medicated troches, not available on the market, for pediatric patients?

- a. True
- b. False

54. Which one of the following statements is correct concerning the filling of a Schedule II controlled substance prescription?

- a. Clinic pharmacies may fill prescriptions for Schedule II controlled substances.
- b. If the patient indicates they only want one-half of the Schedule II controlled substance amount written for, they may pick up the remainder of the prescription within 7 days from the date the prescription was originally filled.
- c. If a patient is a terminally ill patient confined to a hospice program or a skilled nursing facility and has a prescription order for a schedule II controlled substance, you may upon reliable information about the patient's condition fill the prescription for less than what was written for and may furnish the remainder of what is left on that prescription within sixty (60) days from the date it was written by the prescriber.
- d. All Schedule II controlled substances must be kept or stored in a special locked unit or vault in the pharmacy, and a perpetual inventory must be taken on them daily.
- e. Schedule II prescription records in California can be filed with Schedule III, IV and V prescription records as long as they contain a stamped on, one inch, red letter "C" in the lower right hand corner.

55. If you were to dispense on a refill a prescription for *Valium 5 mg.*, which of the following labels or information would you be required by law to provide to the patient?

- I. A patient medication guide.
  - II. A verbal consultation.
  - III. An auxiliary label stating, "*THIS MEDICATION MAY CAUSE DROWSINESS -THEREFORE, BE CAREFUL WHEN OPERATING A VEHICLE.*"
  - IV. An auxiliary label stating, "*THIS PRESCRIPTION IS NOT TO BE TRANSFERRED TO ANOTHER PERSON OTHER THAN THE PERSON IT WAS PRESCRIBED FOR.*"
- a. I and II only
  - b. II and IV only
  - c. I, II and III only
  - d. III and IV only
  - e. II, III, and IV only

56. Concerning the compounding of drug products for a licensed prescriber's office use, which one of the following is least correct?
- a. Reasonable quantities of a compounded drug product may be prepared for a prescriber's office practice.
  - b. The prescriber may provide no more than a one week supply to a patient from the compounded product prepared by the pharmacy.
  - c. The pharmacy may only place up to a 180 day expiration date on the compounded product or the expiration date of any component of the compound that will expire earlier than the 180 days.
  - d. The pharmacy must label the compounded product with the name and amount of each ingredient, the total weight or volume of the compounded product, the appropriate expiration date, and that it is for the "Prescriber's Office Use."
57. The federal form sent to each pharmacy for purposes of performing a once every two year inventory of all Schedule Controlled Substances must be kept by the pharmacy for at least:
- a. One year after performing the inventory of all controlled substances.
  - b. Two years after performing the inventory of all controlled substances.
  - c. Three years after performing the inventory of all controlled substances.
  - d. Five years after performing the inventory of all controlled substances.
  - e. Seven years after performing the inventory of all controlled substances.
58. If you receive a prescription for a Scheduled controlled substance on a regular prescription (non-security Rx form), you may fill it one time as an accommodation to both the physician and the patient; but must call the physician and communicate to him/her that you are making this one-time accommodation, and that all his/her subsequent orders for Scheduled controlled substances must be on the special security prescriptions.
- a. True
  - b. False



59. According to a California law that took effect 1/1/99 regarding the writing of a Schedule II controlled substance on a regular prescription blank, which one of the following statements is least correct?
  - a. The prescription must have written on it: *Exemption 11159.2* since this type of prescription can only be for a terminally ill patient.
  - b. The prescription must be for a terminally ill patient.
  - c. The prescription may have all the information either typed or handwritten on it, and the prescriber authorizing the Schedule II drug must sign and date the prescription in his or her own handwriting, and would only be for a terminally ill patient with the "*Exemption 11159.2*" written on it.
  - d. A copy of the prescription must be mailed to the State Department of Justice at the end of the month.
  - e. The prescription information must be electronically transmitted to a central data base collection agency authorized by the DEA in accordance with the CURES Program no later than on a weekly basis.
  
60. An optometrist who has a TPA-certification (has the letter "T" at the end of their license number) may not write for which one of the following prescription drug items even if they have a DEA registration number?
  - a. 3-day supply of hydrocodone in combination with a non-scheduled controlled substance such as acetaminophen.
  - b. Topical anti-inflammatory drugs (including topical steroids).
  - c. Topical anti-glaucoma drugs.
  - d. I.M. cephalixin
  - e. Oral acyclovir
  
61. In doing a Schedule controlled substances inventory as required by federal law, which one of the following is not true?
  - a. You must maintain the completed inventory as a record to be kept in your pharmacy for 3 years from the date the inventory was taken.
  - b. You must provide an accurate count of all your Schedule II controlled substances.
  - c. You may provide estimate counts of all your Schedule III, IV and V controlled substances for bottles of 100 (tablets or capsules) or less.
  - d. You must send a copy of the completed inventory to your regional DEA office.
  - e. You must do an accurate count of all your Schedule III, IV and V controlled substances (tablets or capsules) for bottles of 1000 that are open.

62. If a pharmacist or a pharmacy is issued a citation by a Board inspector, the pharmacist or pharmacy may contest any or all aspects of the citation by appealing to the Board in writing within 60 days of the issuance of the citation. If done within 60 days, the Board is obligated to set up an office conference with the party cited.
- True
  - False
63. If the Board of Pharmacy issues, usually through one of its Board inspectors, an "order of abatement" to you as the pharmacist-in-charge and to the pharmacy, this means which one of the following:
- That the pharmacy must be closed down.
  - That the pharmacy must pay a proposed fine.
  - That the pharmacy must return prescription drugs back to the wholesaler or manufacturer.
  - That the pharmacy must correct some existing problem.
  - That the pharmacy must file for a new pharmacy permit.
64. Mrs. Jones, who has been a long time client of your pharmacy, comes in with a prescription for *"Ibuprofen 400 mg, #50, one tablet three times a day after meals as needed for pain."* Although you have an inexpensive generic *Ibuprofen*, you strongly suggest that she buy a bottle of 100 tablets of a generic *Ibuprofen 200 mg tablets* available as a nonprescription drug. The reason for this recommendation is that it will cost Mrs. Jones less money than the prescription since she is a "self-pay" client with no prescription insurance plan. You also advise her to take two tablets of the nonprescription substitute three times a day after meals. What you have done is:
- A violation of the law, but in the best interest of the patient.
  - A violation of the law, and not in the best interest of the patient.
  - Not a violation of the law, and in the best interest of the patient.
  - Not a violation of the law, but not in the best interest of the patient.

65. Which one of the following statements is most correct regarding the provision of Emergency Contraceptives over-the-counter under the Plan B Program?
- Under Plan B the emergency oral contraceptive agent may be sold to a patient under the age of 16 years.
  - The pharmacist who sells the emergency contraceptives under Plan B must be certified by receiving at least 10 hours of educational training on this topic.
  - Under Plan B there are about 10 different emergency oral contraceptive agents with different active ingredients that may be sold over-the-counter.
  - Under Plan B the pharmacist may charge up to a \$10 administrative fee when selling the emergency contraceptive agent over-the-counter.
  - The purchaser of the Plan B emergency oral contraceptive may purchase more than one package over-the-counter whether it is for immediate or for future use.
66. Which one of the following statements is not true regarding a pharmacist's dispensing of replaceable contact lenses?
- The pharmacy, before dispensing replacement contact lenses, shall register with the Medical Board of California at the time of initial application of license.
  - The prescription for replacement contact lenses must contain the state license number of the prescribing practitioner before filling.
  - The expiration date on the label affixed to the prescription must explicitly state an expiration date of not more than 3 years from the date of the last prescribing examination.
  - There may be no generic substitution of the replacement contact lenses if a specific brand or name is written for.
  - The pharmacist upon dispensing the replacement contact lenses must provide the patient with the following written notice, "*Warning – If you are having any unexplained eye discomfort, watering, vision change, or redness, remove lenses immediately and consult with your eye care practitioner.*"

67. If a Schedule III controlled substance prescription indicates that it may be refilled *prn*, then the pharmacist must respond to this designation in the following way:
- The pharmacist may fill the original prescription, but will be unable to refill the medication.
  - The pharmacist may fill the original prescription, and just refill one time.
  - The pharmacist may fill the original prescription, and may refill the prescription up to 5 times within 6 months.
  - The pharmacist may not fill the prescription at all – neither the original nor provide any refills.
68. As a pharmacist you inappropriately fill a prescription for a patient. The prescription called for *Vasotec 10 mg one daily*, you mistakenly filled the prescription with *Vasotec 5 mg* tablets. You happen to find out about your error 2 weeks after you dispensed the *Vasotec 5mg* to the patient. After thinking about it as to whether or not to contact either the patient or the patient's doctor about the error, you decide the matter is at best inconsequential since the patient is at least getting the drug *Vasotec*. By not contacting the patient and correcting the error, this would be considered:
- A violation of the law, but in the best interest of the patient.
  - A violation of the law, and not in the best interest of the patient.
  - Not a violation of the law, and in the best interest of the patient.
  - Not a violation of the law, but not in the best interest of the patient.
69. When a physician assistant (P.A.) writes a prescription for a drug he or she is authorized to write for under a physician established protocol, the pharmacy in the filling of that prescription does not have to include the name of the authorizing physician on the label affixed to the prescription vial – just the name of the P.A. need be present on the label.
- True
  - False

70. A patient comes into your pharmacy with a prescription for *Oxyrsoralen 10 mg Capsules, # 50, Take as directed*. You note that you do not have the drug in your regular stock, but you happen to have a box of samples containing 200 *Oxyrsoralen 10 mg Capsules* given to you by the pharmaceutical company's drug representative six months ago. The patient tells you that she has been to ten other pharmacies and none of them had the drug in stock. You decide to prepare the prescription for her for the 50 capsules of *Oxyrsoralen 10 mg* from your sample stock and charge the patient a nominal fee of \$10.00 primarily for preparing and dispensing the drug as a prescription. Your action as a pharmacist in this matter is:
- A violation of the law, but in the best interest of the patient.
  - A violation of the law, and not in the best interest of the patient.
  - Not a violation of the law, and in the best interest of the patient.
  - Not a violation of the law, but not in the best interest of the patient.
71. A physician's office calls you with a new prescription order for a patient. The call to the pharmacy is made by the physician's secretary who is authorized by the physician to call the prescription into the pharmacy. Considering this call to the pharmacy, which one of the following choices is least correct?
- The pharmacy may honor the prescription even though it was the physician's secretary calling it in.
  - The pharmacist-intern may take the called-in prescription and must reduce it to writing immediately and further indicate the name or initial of the party calling it in.
  - Assuming that the pharmacist wants to validate that the prescription called in is correct, he or she may have a pharmacy technician or clerk call to validate that the original call and information provided was correct.
  - If the pharmacist has any doubt about the authenticity of the prescription and/or if the secretary has the authority to call it in, the pharmacist is obligated to confirm the legitimacy of the prescription with the licensed prescriber.



72. A patient comes into your pharmacy with a prescription for "Inderal 10 mg" tablets. You have three different generic versions of this same drug by different manufacturers on your shelves along with the trade named brand of *Inderal 10 mg*. The prescriber has not indicated any restrictions such as a "Do Not Substitute" request. As a result which one of the following actions in the filling of this prescription is the most appropriate and consistent with the laws of California?
- Even though there is no indication on the face of the prescription "Do Not Substitute," you may still not substitute under any conditions since the prescriber wrote for a specific trade name drug.
  - If you want to substitute with a generic, you must first contact the prescriber to attain his or her permission.
  - The law allows you to substitute for a less expensive generic substitution without contacting the prescriber or without receiving the patient's permission.
  - In order to substitute the generic drug equivalent for *Inderal 10 mg* you are required to ask the patient's permission to dispense the generic and communicate to the patient that it will save him or her money if such a substitution is made.
73. If you have either a change of name or address you must notify the board of pharmacy of such change in name or address within what period of time?
- Within 72 hours.
  - Within 14 days.
  - Within 30 days.
  - Within 60 days.
  - Within 6 months.
74. Which one of the following statements is false regarding the sale of dangerous veterinary drugs?
- The veterinary drug, pursuant to a prescription by a licensed veterinarian, may be prepared and dispensed by an exemptee trained in this area who is licensed by the Board of Pharmacy.
  - May be sold without a prescription.
  - May only be sold by prescription.

75. Which one of the following is not a legal requirement for a community pharmacy having a pharmacy technician?
- That the pharmacy tech must wear an identification badge noting that he or she is a "pharmacy technician" while working in the capacity of a pharmacy tech.
  - That the pharmacy tech must pass an examination administered by the State Board of Pharmacy in order to be granted pharmacy technician certification.
  - That the pharmacy employing the pharmacy tech have written policy, procedures and a job description for pharmacy techs employed at that community pharmacy.
  - That a community pharmacy may have the pharmacy technician mix pharmaceuticals.
  - That the community pharmacy may have only one pharmacy technician for the first pharmacist on duty, and may increase by two pharmacy technicians for each additional pharmacist after the first pharmacist. Thus, if there are 3 pharmacists on duty at the same time, there may be present 5 pharmacy technicians.
76. In which one of the following ways is a surgical clinic different than a multispecialty clinic in regards to providing pharmacy-related services to clinic patients?
- If both carry prescription drugs, then both must be licensed by the California State Board of Pharmacy.
  - Both may dispense whatever amount of a prescription drug is ordered for a patient pursuant to a prescription for take home purposes.
  - Neither can dispense Schedule II controlled substances to a patient for take home purposes.
  - Both must have a consultant pharmacist review, on an annual quarterly basis, how well the clinic complies with applicable pharmacy laws.
  - Both may order Schedule III, IV and V controlled drugs for purposes of use in the clinic and for dispensing.

77. M.R. is a 16 year old female who early in the morning came into your pharmacy to drop off a prescription written by her doctor for *Ortho-Novum 1/50* birth control tablets, a 3 month supply. Her parents have no idea that she is receiving this medication, but are aware that their daughter and her boyfriend are staying out late on weekend nights, and that the daughter is not responsive to her parent's request to not see the boyfriend. The mother has heard from her neighbor that she saw M.R. go into your pharmacy and give you a prescription to be filled. The neighbor does not know what the medication is for, but knows that the prescription is still at the pharmacy waiting to be picked-up. After the mother hears this, she races down to your pharmacy and asks you what her daughter had the prescription filled for and that she wants to pick it up for the daughter. After checking what the prescription is for, you feel uncomfortable about either selling the prescription to the mother or telling her what it is and what it is generally used for. Your decision not to tell nor to sell the prescription to M.R.'s mother would be considered:
- A violation of the law, and not in the best interest of the patient (M.R.).
  - A violation of the law, but in the best interest of the patient (M.R.)
  - Not a violation of the law, and in the best interest of the patient (M.R.)
  - Not a violation of the law, but not in the best interest of the patient (M.R.).
78. If for some reason you forget to renew your license on the due date, it may not be reinstated, restored, or renewed after what period of time from the date renewal was due?
- Six months
  - One year
  - Two years
  - Three years
  - Five years

79. When there is an electronic transfer of a prescription by means of "E-mail," the prescriber's address, license classification and federal registry number may be omitted if they are on file and readily retrievable in the receiving pharmacy.
- True
  - False
80. A patient comes into your pharmacy on a Friday evening with a request to refill her prescription for *Ortho-Novum 1/50*. The patient has been getting this medication for the last six months, but has no further refills and her physician is not available till Monday. The patient has had no major problems while on the drug regimen and has complied appropriately in taking the drug over the last six months. Which one of the following choices would be considered the best choice and would be in compliance with the State's laws?
- Tell the patient that you cannot give her a refill or any amount of the drug until her physician can be reached and approves of a refill. Further advise her on the use of an OTC contraceptive as an alternative protective measure.
  - Provide the patient with 3 tablets of the medication until her physician can be reached on Monday to approve of further refills.
  - Provide the patient with a one month supply of the prescription and contact her physician on Monday to let the physician know what you have done and request further refills.
  - Provide the patient with a 6 month refill supply and advise the physician on Monday on what you have done.
81. If a patient runs out of his/her Schedule III prescription drug which he/she appears to need for pain control, and there are no refills, and the prescriber cannot be contacted, the pharmacist may:
- Provide the patient with a 72 hour supply only.
  - Provide the patient with a reasonable supply of the drug.
  - Provide the patient with the exact amount on the prescription in accordance with the law that prevents deviation from what was written for on the prescription.
  - Since there are no refills, no drug should be provided to the patient without first contacting the prescriber for his/her approval to continue the drug.

82. Concerning the posting of drug prices in a community pharmacy:
- It is required by law that the prices for all highly dispensed prescription drugs must be posted in the front window of the business entity that has a pharmacy present in it.
  - It is required by law that the prices for all highly dispensed prescription drugs must be posted in the area nearest the pharmacy in a conspicuous space.
  - It is required by law that the price for all prescription drugs the pharmacy carries not only be posted in a conspicuous place in proximity to the pharmacy, but a notebook containing all the prices for given quantities and strengths of the drug also be available on the pharmacy counter for patients to view.
  - There is no law presently requiring that the pharmacy post its prescription drug prices or have a notebook of drug prices for consumers to review; but only make the prescription drug prices available verbally upon a consumer's request for the price.
83. If a pharmacy is under a court-ordered "receivership," the owner of the pharmacy must notify the Board of Pharmacy within 30 days of the institution of the "receivership."
- True
  - False
84. If a customer who comes into your pharmacy wishes to purchase an OTC drug product containing pseudoephedrine, that customer may only purchase up to which one of the following amounts per a single transaction?
- 1000 mgs
  - 3.6 grams
  - 6.5 grams
  - 9.8 grams
  - 12.5 grams
85. Concerning the "Pharmacy Self-Assessment Form" issued by the California State Board of Pharmacy, which one of the following is correct:
- The form is to be filled out on an annual basis, and a copy kept at the pharmacy for 2 years.
  - The filled-out form is to be returned to the Board of Pharmacy within 30 days of receipt by the pharmacy.
  - The form must be filled out before January 30<sup>th</sup> of every even numbered year.
  - Any employee of the pharmacy may fill-out the form.
  - The pharmacist-in-charge is responsible for the filling-out of the form every odd numbered year before July 1st.



86. Which one of the following statements is least correct regarding the obligation of the pharmacist giving prescription price information to a requesting customer who brings into your pharmacy six (6) prescriptions and asks that you provide the price of each before filling?
- The pharmacist may require that the consumer's request be in writing.
  - A pharmacy is not required to respond to more than 3 requests of this type from anyone person within a six month period.
  - The pharmacist must respond to the consumer's request within a reasonable time (10 days is considered reasonable).
  - The pharmacist may charge a reasonable fee for first looking up the prices per prescription when the patient requests such prices before having his prescriptions filled, plus the regular charge if the patient decides to fill the prescriptions.
  - The pharmacy may charge a reasonable fee for each prescription price quotation even though the requesting customer does not get the prescriptions filled and as long as they are advised of this charge.
87. Which one of the following is least correct regarding a pharmacist setting-up and participating in an "immunization" program.
- There must be a physician in charge.
  - The physician does not have to be present on the premises during the time the immunizations are being given.
  - There must be a protocol that includes an outline of what class of patients are to receive the specific immunizations, the class that are not to receive the immunization, and what action is to be taken if a recipient is injured as the result of the immunization.
  - The physician does not have to provide a prescription for each individual who is the class that qualifies to receive the immunization.
  - Under the National Vaccine Injury Compensation Program the pharmacist is protected and will not be held liable for any injury caused by the immunization whether it is an adverse or allergic reaction caused by the immunization product, or is due to some negligent act done by the pharmacist giving the immunization injection.

- 88.** If a pharmacist wishes to dispense disposable contact lenses, which one of the following professional Boards has jurisdiction in the registering of a pharmacist to allow them to dispense disposable contact lenses pursuant to a prescription order for such disposable lenses?
- a. Calif. Board of Pharmacy
  - b. Calif. Medical Board
  - c. Calif. Optometry Board
  - d. Calif. Optician Board
  - e. A pharmacist is not allowed to dispense disposable contact lenses under any circumstances.
- 89.** Which one of the following statements is least correct regarding a pharmacy's Quality Assurance Program regarding maintaining records on medication errors?
- a. Once the medication error report form is complete, a copy must be sent to the Calif. State Board of Pharmacy within 30 days after the discovery of the medication error incident.
  - b. On the medication error report prepared by the pharmacy, the names of personnel involved do not have to be stated in the report.
  - c. A medication error report must only be prepared if the patient receives the prescription that has an error. No medication error report must be prepared if the error is caught and corrected before the patient receives that prescription that has some error associated with it.
  - d. An investigation by a pharmacist for each medication error shall occur no later than 2 business days from the date the error was discovered, and a medication error report prepared.
  - e. Any medication error report that is prepared must be kept as part of the pharmacy's records for at least one year.

90. The Calif. Labor Codes now places the pharmacist in the category of a non-exempt employee. There are, however, four exceptions to the non-exempt employee status stated in the labor codes. Which one of the following is also an exception to the non-exempt status of the pharmacist, but is not stated as such within the labor codes?
- a. The exclusion of those in executive or administrative positions which allows the pharmacist-in-charge to be classified as an exception or an exempt employee under the labor codes.
  - b. Any changes agreed to through collective bargaining associated with labor union negotiations.
  - c. Working 10 hours a day within a 40 hour work week if agreed to by at least 2/3rds of the employed pharmacy staff.
  - d. In an emergency situation or where there is a need to protect life.
  - e. Working 8 hours a day and 40 hours a week at one pharmacy and then working 2-eight hour shifts at another pharmacy independently owned and operated relative to the first pharmacy.
91. Concerning the sale by a pharmacy of any ephedrine-like product that is a herbal agent, which one of the following restrictions is the most correct?
- a. The person purchasing the herbal ephedrine containing product must be 21 years or older.
  - b. The herbal products containing ephedrine or ephedrine-like compounds do not have to show the amount of the ephedrine or ephedrine-like substance on the label.
  - c. The person purchasing the ephedrine containing herbal product must be 18 years or older.
  - d. The herbal products containing ephedrine or ephedrine-like substances do not have to have the same information on their label (e.g. cautions regarding the use of the product) as do the FDA approved OTC ephedrine products.
  - e. All herbal agents containing ephedrine or ephedrine-like products are to be removed from the over-the-counter market.

92. In a telephone transfer of the remaining refills on a patient's prescription for a nonscheduled drug from one pharmacy to another, of the following which statement below is most correct?
- a. It can only be transferred one time even if there are remaining refills after refilling it at the second pharmacy.
  - b. Those involved in the telephonic transfer need not be pharmacists or pharmacist interns.
  - c. The pharmacy sending the order by telephone to the other pharmacy may still reserve remaining refills, if there are any on the original prescription. Thus, the prescription does not have to be canceled or voided if there are remaining refills after the transfer of only one of those refills.
  - d. The sending pharmacist must not only indicate on the back of the prescription that he or she transmitted the prescription information to the new pharmacy, but must also record the name of the receiving pharmacist.
  - e. When the sending pharmacist transfers the remaining refills to the new pharmacy, the receiving pharmacist may not fill the prescription unless he or she contacts the patient's prescriber for authorization.
93. When you as a pharmacist dispense a prescription to a patient applying the new labeling standards to the label you affix to the patient's prescription vial, in order to get all the information required on the label you may use a *sans serif* type font of "8."
- a. True
  - b. False
94. Which one of the following drugs would generally not require an auxiliary label as proscribed by law to advise the patient of a specific warning?
- a. Darvon
  - b. Nitrostat
  - c. Parnate
  - d. Pepcid
  - e. Cystospaz

95. Which one of the following is the more correct answer regarding the pharmacy's responsibility of providing drug consultation for a new prescription drug that is prescribed for the first time and is to be delivered to a patient's home?
- The pharmacist must call the patient directly, and only speak with the patient for whom the drug was ordered for, orally advising that patient on what is required under the "Consultation Law" for California.
  - The pharmacist must call the patient's home, and may provide the oral consultation (pertaining to items required by Calif. Law) to any member of the patient's household.
  - The pharmacist must send a written statement along with the prescription that indicates to the patient that if they have any questions about their medication they can call the pharmacy at a given telephone number and speak with the pharmacist for consultation advice on the new medication.
  - The pharmacist, in lieu of an oral consultation, must send the patient for whom the prescription is intended for, a detailed written description of those items that would otherwise be covered in an oral consultation.
  - The pharmacist cannot deliver a new prescription, the patient must come into the pharmacy to receive the oral consultation and personally be dispensed the new prescription drug.
96. Which one of the following statements is most correct regarding the sale of "ephedrine-like" products over the counter?
- No more than 12 packages of the ephedrine-like product may be sold over-the-counter per transaction.
  - No more than 9 grams of the ephedrine-like product may be sold per transaction.
  - The ephedrine-like products do not have to be kept behind the pharmacy counter nor do they have to be sold by a pharmacist or be under a pharmacist's supervision or the sale be registered in a log book requiring the customer to sign.
  - The customer is restricted to not more than a 9 gram purchase limit each month when purchased over-the-counter.
  - If an ephedrine-like drug is ordered pursuant to a prescription and the prescription amount dispensed will exceed 9 gram limit, this sale must be reported to the State Department of Justice, Bureau of Narcotic Enforcement.



97. In preparing extemporaneous unit dose blister packs within your pharmacy for a tablet to be used in a skilled nursing facility, what date must you print onto your unit dose packages for those tablets if the manufacturer's expiration date is 16 months from today's date?
- An expiration date of 3 months from today's date.
  - An expiration date of 4 months from today's date.
  - An expiration date of 6 months from today's date.
  - An expiration date of one year from today's date.
  - An expiration date of 16 months from today's date.
98. Concerning the storage of pharmacy records at a storage site other than at the licensed pharmacy, which one of the following is most correct?
- This may be done only if approved by the Board in the form of a waiver, and that a separate license must be issued by the Board for the off-site storage of the records.
  - The storage of pharmacy records at a site other than the licensed pharmacy is totally disallowed by the Board, and no such waiver can be provided by the Board.
  - A licensee who does receive a waiver from the Board for off-site storage of prescription records, and has his/her waiver canceled by the Board because of noncompliance, may never again receive a second waiver by the Board.
  - The storage of pharmacy records at a site other than at the licensed pharmacy is allowed upon the issuance of a special waiver by the Board of Pharmacy. No additional license is required by the Board other than a waiver approval by the Board of Pharmacy.
  - If prescription records are required by the Board of Pharmacy contained in an off-site facility, those records must be produced immediately or within 6 hours of the request by the Board.
99. When a pharmacy is sold to a new owner, the new owner can notify the Pharmacy Board to acquire a temporary permit in order to maintain a continuous operation. This temporary pharmacy permit is good for what period of time?
- 30 days
  - 60 days
  - 120 days
  - 180 days
  - 365 days

100. Which is the most correct concerning the law that allows a pharmacist to temporarily leave the area of the pharmacy when he or she is the only pharmacist on duty and to allow all other ancillary pharmacy personnel within the pharmacy to remain?
- That pharmacist cannot take any longer than a 15 minute leave.
  - In a chain operation the decision as to whether or not the pharmacist can leave temporarily will be the decision of the chain's administration, and will not be up to the individual pharmacists in each store.
  - During the pharmacist's temporary absence, no prescription medication may be provided to a patient unless the prescription is a refill medication that the pharmacist has checked, approved for release to the patient, and did not require a patient consultation by the pharmacist.
  - The pharmacist-intern, during the temporary absence of the pharmacist, may still consult with patients when they pick-up their new prescription medications.
  - The present law does not require that written policies and procedures be in place outlining the duties of the ancillary staff during the period of the temporary absence of the pharmacist from the pharmacy.
101. A prescriber may write a prescription that causes a pharmacist to prepare a prescription label that is false if, in the medical judgment of the prescriber, the labeling is appropriate for the proper treatment of the patient.
- True
  - False
102. According to the State's Quality Assurance law, medication errors must be investigated within what period of time after they occur or after they are discovered?
- Investigated within 24 hours of their discovery.
  - Investigated within 48 hours of their discovery.
  - Investigated within 72 hours of their discovery.
  - Investigated within 7 days of their discovery.
  - Investigated within 30 days of their discovery.

103. Regarding the pharmacy services for a hospital with 100 beds or less, which one of the following is most correct?
- a. A hospital of 100 beds or less may not have Schedule II drugs.
  - b. A hospital of 100 beds or less must have a full time pharmacist employed.
  - c. A hospital of 100 beds or less must have at least the employment of a part-time pharmacist.
  - d. A hospital of 100 beds or less must have at least a consultant pharmacist on staff.
  - e. A hospital of 100 beds or less does not require a pharmacist at all, since a nurse can be in charge of all drug related activities.
104. In the event that a pharmacy permit is either revoked by the Board, or the permit holder advises the Board that he or she plans to discontinue doing business, the permit holder shall, within what number of days, notify the Board and arrange for the transfer of all prescription drugs to either another pharmacy or licensed wholesaler?
- a. Five days.
  - b. Ten days.
  - c. Fifteen days.
  - d. Thirty days.
  - e. Sixty days.
105. A pharmacy may order Schedule II drugs from an out-of-state wholesaler, manufacturer, or other supplier as long as the pharmacy forwards a true and correct copy of the order, contract, or agreement for procurement of such Schedule II drugs to which one of the following agencies within what period of time?
- a. California State Board of Pharmacy within 30 days of transmitting the order.
  - b. California State Board of Pharmacy within 72 hours of transmitting the order.
  - c. California Regional DEA Office within 72 hours of transmitting the order.
  - d. California Regional DEA Office within 30 days of transmitting the order.
  - e. State's Attorney General's office within 24 hours of transmitting the order.

106. According to the law on the “Reporting of Medication Errors,” this law specifically requires which one of the following:

- a. That the FDA be advised of all “Medication Errors” and “Adverse Drug Reactions” that occur at a pharmacy starting on January 1, 2002.
- b. That each pharmacy, as its only responsibility, must maintain a record of all “Medication Errors” for a one year period from the date of recording such medication errors.
- c. That besides maintaining a one year written record for each medication error, the pharmacy must also develop policy and procedures describing the documentation of such medication errors, and how these errors shall be utilized in developing a quality assurance program to attempt to decrease such errors over time.
- d. That besides maintaining a one year written record for each medication error, and developing policy and procedures describing the documentation of the errors and how these errors shall be utilized in developing a quality assurance program to help decrease such errors, the pharmacy shall also have in place a reporting of these errors to the Board of Pharmacy and the FDA.
- e. That besides maintaining a one year written record for each medication error, the pharmacy will be required to report these errors on a monthly basis, at the end of each month to the State Board of Pharmacy.

107. A pharmacy that performs a State Board of Pharmacy required “*Self-Assessment Survey*” must respond to the survey how frequently and keep the answered survey for what length of time?

- a. Survey to be filled-out every 3 years and kept for 4 years.
- b. Survey to be filled-out every year and kept for 2 years.
- c. Survey to be filled-out every 2 years and kept for 3 years.
- d. Survey to be filled-out every 4 years and kept for 6 years.
- e. Survey to be filled-out every year and kept for 3 years.

108. A patient brings in a special security prescription for Meperidine 60 mg tablets #30 on the date the prescription was written by the prescriber. The prescription is legitimate, and written by prescriber licensed by the DEA. The pharmacist believes the prescriber meant meperidine 50 mg tablets since it comes in that strength as well as a 100 mg strength. The pharmacist calls the prescriber who admits he made a mistake and really wants the 50 mg tablets. All other information on the prescription is correct. As a result of this mistake upon the part of the physician, the pharmacist must do which one of the following in order to be in compliance with the law?
- a. Not fill the prescription and ask the patient to return to the physician to get a newly written prescription for the meperidine 50 mg.
  - b. Fill the prescription, cross out the error on the security prescription, initial it indicating that the error was reconciled by the prescriber, and have the prescriber within 7 days acknowledge the mistake by faxing to the pharmacy a regular prescription with the prescriber's signature noting the correction.
  - c. Fill the prescription as an emergency, and request that the physician forward a replacement security prescription to the pharmacy with the correction of meperidine 50mg within 72 hours from the date it was written.
  - d. Fill the prescription as an emergency, and request that the physician forward a replacement security prescription to the pharmacy with the correction of meperidine 50 mg within 7 days from the date it was written.
  - e. Notify the prescriber to inform him or her of the mistake; if the mistake is acknowledged by the prescriber, make the change on the security prescription and document that you called prescriber to make the correction. You do not have to mail the prescription back to the prescriber for a second signature from the prescriber acknowledging that the mistake was corrected.



109. Regarding the requirements for pharmacy in maintaining patient confidentiality as established under HIPAA (*Health Insurance Portability and Accountability Act*), every patient who comes to your pharmacy for their prescriptions must be given written notice of what his or her privacy rights are under HIPAA. While it is beneficial to have the patient sign the notice, his or her refusal to sign will not prevent them from receiving the usual pharmacy services.
- True
  - False
110. A Certified Nurse Midwife (CNM) if acting pursuant to a physician's protocol may not do which one of the following:
- May furnish a prescription for a Schedule III controlled substance without being registered with the DEA since it is pursuant to the physician's protocol allowing this drug to be ordered for a given patient.
  - May furnish a prescription for a Schedule II controlled substance provided that they are registered with the DEA and it is in accordance with the physician's protocol and is furnished in connection to a prenatal, perinatal, family planning or maternity service.
  - Order, sign for, and furnish samples pursuant to a physician protocol allowing such activities.
  - May furnish antibiotics to a female pursuant to a prescriber's protocol who is examined by the CNM and diagnosed with sexually transmitted Chlamydia.
  - May furnish antibiotics to the sexual partner of a patient who is diagnosed with a sexually transmitted Chlamydia infection without an examination of that patient's sexual partner.
111. Regarding the State issued single security prescription form for ordering controlled substances for patients, which one of the following statements is most correct?
- Only orders for Schedule II prescription drugs must be written on this form by the prescriber.
  - Only orders for Schedule II and III prescription drugs must be written on this form by the prescriber.
  - Only orders for Schedule II, III, and IV prescription drugs must be written on this form by the prescriber.
  - All orders for controlled substance, including Schedule V controlled substance, prescriptions must be ordered on this form by the prescriber.

**112.** The husband of one of your patients comes into the pharmacy with two prescription containers belonging to his wife. He explains to you, that these drugs were ordered upon discharge of his wife from the hospital. Unfortunately, his wife died at home the day after discharge and never took any of the two medications, He wishes to return them to the pharmacy and be credited for what he paid originally, which was close to \$250 for both. The containers of both of the drugs appear not to have been opened by the patient. Under these circumstances you may take the drugs back, reimburse the husband and reuse them pursuant to a prescription order for another patient.

- a. True
- b. False

**113.** A hospital of 100 or less beds that does not have outpatient pharmacy services, and purchases its prescription drugs for inpatient care, is not allowed to do which one of the following:

- a. Dispense drugs for patients treated for emergency medical problems after visiting the hospital's emergency room.
- b. Dispense drugs for outpatient use pursuant to a physician's prescription.
- c. To treat patients with the prescription drugs that are registered as inpatients of the hospital.
- d. Dispense drugs to outpatients where the hospital is in isolated and in a rural area.
- e. May not sell drugs to outpatient or community pharmacies where there is a patient who needs the drug on an outpatient basis but the community pharmacy does not have the drug in stock to accommodate that patient.

**114.** A pharmacist may now apply for a DEA number in order to write prescriptions, pursuant to a prescriber-created protocol, for Schedule II, III, IV and V controlled substances, and be the sole signature on the prescription.

- a. True
- b. False

115. Which one of the following statements is correct regarding the use of a prescription drug for an "off-label" use.?
- a. The FDA requires that the drug manufacturer submit a new drug application (NDA) for the drug before it can be promoted for "off-label" use.
  - b. The FDA requires that the drug manufacturer submit promotional materials for review before allowing the drug to be promoted for "off-label" use.
  - c. The FDA requires that the drug manufacturer submit reports semiannually on any new industry promotional activities related to the drug.
  - d. The FDA will generally have little control over a drug used for "off-label" use as long as it has been shown to be effective and safe for "off-label" use based upon information contained in a combination of well-respected sources, and the drug has an "off-label" effect in the management of life threatening or disabling diseases.
116. Last night your pharmacy experienced a fire that caused fire damage in the front area of your pharmacy, but the fire did not enter the pharmacy area. Your entire store was filled with smoke, and when the fire occurred the sprinkler system was activated causing about two inches of water to accumulate on the floor throughout the entire store, including the pharmacy. Because the water was initially hot due to the fire heating up the water pipes, steam was also generated throughout the store. After the fire is put out, you come to find that none of the drugs in the pharmacy area were destroyed by the fire, but many of the packages containing the drugs are damp or moist. Also, most of the drugs on the shelves of the pharmacy are either covered with ashes or smell from smoke. Which choice below best describes your responsibility as a result of this fire?
- a. As long as the drug containers are not burnt and can be dried-out, the contents of the containers may still be used to fill prescriptions; and since no drugs were lost in the fire, there is no need to report any loss to either the State Board of Pharmacy or the DEA.
  - b. Only the drug containers that have ashes on them cannot be used to fill prescriptions.
  - c. Only the drug containers that have moisture on them cannot be used to fill prescriptions.
  - d. Any drugs that are considered to have been seriously affected by the fire must be reported to both the State Board of Pharmacy and the DEA immediately.
  - e. Every drug in the pharmacy is considered lost as a result of the fire, and therefore the losses must be reported to both the Board of Pharmacy and to the DEA (if scheduled controlled substances are involved in this fire).

117. An unreasonable delay for the patient in the filling of a prescription the patient may need to take on an immediate basis can be construed as a medication error under Title 16, California Code of Regulations, Section 1711?
- True
  - False
118. Which one of the following is the most correct answer regarding the incorporation of a pharmacy quality assurance program for drug error reporting that is in compliance with the law?
- Drug errors that are reported by the pharmacy must be forwarded to the State Board of Pharmacy monthly.
  - It is considered a drug error and needs to be written up even if the error is corrected before the patient has the medication dispensed to him or her.
  - The names of all employees involved in causing the error must be on the final drug error report.
  - Once the error is discovered, the pharmacy has two working days to investigate the error, and then to write up the report that must be kept as record in the pharmacy for one year.
  - The major purpose of writing up the medication error report under the quality assurance program is to ensure that the pharmacy's insurance company receives a detail assessment of why the error occurred and what was done about it for the purpose of hopefully mitigating money damages if the patient should sue the pharmacy.
119. Which one of the following statements is most correct about a pharmacy that provides a compounding service?
- You may not advertise that you provide a compounding service because of the present law under the Food and Drug Administration Modernization Act (FDAMA) of 1997.
  - You are allowed to compound unapproved products for future use (for not yet identifiable patients) as long as you keep records on these products that have such information as the date of preparation, lot numbers, expiration dates, a formula for the compounded products, etc.
  - You do not need to acquire a separate license from the California State Board of Pharmacy if you are going to do any type of sterile drug product compounding.
  - You may provide large amounts of compounded products to a prescriber's office, per his or her request, in order that that prescriber can dispense large supplies of the compounded product to his or her patients.
  - A compounded product may have an expiration date of one year or less.

120. Which statement is the most correct regarding a pharmacy's compliance with HIPAA?

- a. Each person who receives a prescription from your pharmacy must sign a consent form explaining how the pharmacy's information about them will be used.
- b. Each person who receives a prescription from your pharmacy must be provided a "Notice Statement" explaining how the pharmacy's information about them will be used. It is mandatory that the patient sign a statement that they have received this "Notice Statement," and that this procedure be done each time the patient comes in to pick-up a prescription.
- c. Each person who receives a prescription from your pharmacy must be provided a "Notice Statement" explaining how the pharmacy's information about them will be used. It is mandatory that the patient sign a statement that they have received this "Notice Statement," and that this procedure need only be done once.
- d. Each person who receives a prescription from your pharmacy must be provided a "Notice Statement" explaining how the pharmacy's information about them will be used. If the person does not wish to sign a statement that they have received this "Notice Statement," the pharmacy need only document that the patient received it, and did not choose to sign it. This still allows the pharmacy to continue filling the person's prescriptions even though signed acknowledgement by the person receiving prescriptions did not occur.
- e. A person who does not sign either the consent form or a notice statement explaining how the pharmacy's information about the person will be used, that pharmacy should not fill that person's prescriptions since their signature is a requirement under the HIPAA rules.

121. If you are sued as a pharmacist regarding a pharmacy-related matter and the case against you is settled before it goes to court, beginning at what settlement dollar amount must you report to the Board of Pharmacy that you have settled the pharmacy-related law suit and the amount of the settlement?

- a. At \$1,000.
- b. At \$2,000.
- c. At \$3,000.
- d. At \$5,000.
- e. At \$10,000.



122. An optometrist who is certified to prescribe prescription drugs and has a DEA registration number may write a prescription for all of the following medications except?
- A topical drug to treat open angle glaucoma in a 75 year old male.
  - A topical antibacterial agent for treating conjunctivitis in a 7 month old child.
  - Oral acyclovir for a viral infection in the eye of a 35 year old female.
  - A three day supply of Vicodin® for a 40 year old male who has a scratched cornea.
  - The use of an I.V. Cephlosporin to treat an eyelid sty caused by staph in a 15 year old female.
123. Which one of the following statements is most consistent with the law that addresses whether or not a pharmacist can refuse to fill a prescription on the basis of that pharmacist's religious, ethical or moral beliefs?
- Under no circumstances can a pharmacist refuse to fill a given prescription for a patient ordered by a licensed prescriber.
  - Under very limited circumstances can a pharmacist exercise his or her religious, ethical, or moral beliefs which may only be applied to prescriptions for birth control medications or emergency oral contraception.
  - A pharmacist may exercise his or her religious, ethical or moral beliefs regarding any drug product, and under such circumstances can tell the patient that either the drug is not in stock, or the pharmacy just doesn't carry the drug.
  - The pharmacist who has a religious, ethical or moral belief regarding the dispensing of a drug or category of drugs need not communicate to his or her immediate supervisor that based upon his or her religious, ethical or moral belief he or she cannot provide the drug to a patient with a prescription for such a drug or category of drugs.
  - The pharmacist who has a religious, ethical or moral conviction regarding the dispensing of a given drug or category of drugs must not only provide notice to his or her immediate supervisor regarding that belief, but also the pharmacy must have a policy and procedure that ensures that the patient is to be able to receive the drug in some alternative way in a reasonably expedient manner.

124. Which statement is the least correct regarding the pharmacist who is designated to be the pharmacist-in-charge (PIC)?
- The PIC is required to give a 30 day notice to the Board of Pharmacy if he or she plans to leave working at a pharmacy where he or she is the designated PIC?
  - If one PIC is replacing another PIC, it will be the responsibility of the new PIC to execute a new *Pharmacy Self-Assessment Survey* shortly after starting as the new PIC even though one was completed 2 months ago just prior to the July 1<sup>st</sup> due date by the PIC at that time.
  - A PIC can only serve as a PIC for one pharmacy only at any given time.
  - An owner of a pharmacy may employ an interim PIC for up to 120 days after a permanent PIC leaves the pharmacy operation for another position.
  - A PIC may not be held liable for the inappropriate acts of any of his or her employees acting within the scope of their employment if cited by the Board of Pharmacy, provided that the PIC did not engage in or approve of the inappropriate act, reported the violation to the Board within a timely manner, and took necessary measures to stop and remedy the violation within a reasonable period of time.
125. Concerning veterinary drug-food retailers, which one of the following is least correct?
- The California State Board of Pharmacy is responsible for the licensing of veterinary drug-food retail operations.
  - An operator of a veterinary drug-food retail operation does not need to be a pharmacist, but has status as an "exemptee" with the party in charge being recognized by the Board of Pharmacy as the "exemptee-in-charge."
  - The veterinary drug-food retail license is renewed every 3 years with the Board of Pharmacy.
  - The veterinary drug-food retail operator who is an "exemptee-in-charge" must be at least a high school graduate with training in veterinary drugs with one year experience.
  - If an "exemptee-in-charge" (EIC) should resign from his or her position at the veterinary drug-food operation where he or she has been employed, that operation must report the leaving within 30 days to the Board of Pharmacy.

126. Which one of the following statements is most correct regarding pharmacy clerks?
- a. If there is one pharmacist on duty, there may only be one pharmacy clerk on duty.
  - b. Pharmacy clerks are required to be licensed by the California Board of Pharmacy, and to have at least a high school education.
  - c. A pharmacy clerk may not put back a prescription drug on the shelf after a prescription has been filled and checked by the pharmacist.
  - d. If there is one pharmacist on duty and three pharmacy clerks, only one of those clerks may answer the phone and type prescription labels.
  - e. A pharmacy clerk can both answer the phone to get refill information from a patient, and can receive approvals for refills by the prescriber on a medication the patient is presently on that needs to be refilled.
127. Regarding the electronic transmission of a prescription (both nonscheduled and controlled substance prescriptions) from a prescriber's office computer to your pharmacy computer, which one of the following statements is incorrect?
- a. Only nonscheduled drug prescriptions may be sent by electronic transmission from the prescriber's office to the pharmacy, and not controlled substance prescriptions under any circumstances.
  - b. All prescriptions may be sent by electronic transmission, including controlled substances prescriptions if the controlled substance prescriptions are in conformance with the "e-prescribing" for both the prescriber and the pharmacy.
  - c. If controlled substance prescriptions are sent by "e-prescribing" all information may be typed except for the prescriber's signature, that information must be sent by means of an electronic signature.
  - d. The pharmacy must have the name or initials of the person electronically transmitting the order from the prescriber's office to the pharmacy.
  - e. The prescriber's address, license classification and federal registry number may be omitted from the electronically transmitted prescription if they are on file and readily retrievable in the receiving pharmacy.

128. A new prescription for a Scheduled III, IV, or V controlled substance that has "*prn refills:*"
  - a. May be filled only one time.
  - b. May be filled up to 6 times (the original plus the 5 refills within 6 months).
  - c. May not be filled at all without contacting the prescriber.
129. In regards to the DEA Form 222, which one of the following is the more correct answer?
  - a. The DEA Form 222 is used to order all Schedule II, III, IV, and V controlled substances from the wholesaler.
  - b. The person ordering Scheduled controlled substances using A DEA Form 222 does not have to be a registered pharmacist.
  - c. The first copy of the DEA triplicate Form 222 must be sent to the Department of Justice at the end of the month, while the second copy of the DEA Form 222 remains with the pharmacy ordering the Scheduled controlled substances.
  - d. When a physician needs to order a Schedule II drug for his or her office use, they are not to execute a DEA Form 222 to order the Schedule II drug since they are allowed to use a security prescription to order this category of drug as long as they place on it "*For Office Use.*"
  - e. The DEA Form 222 may not be used to transfer Schedule II controlled substances between pharmacies.
130. A prescription for a Schedule II controlled substance where it is to be partially filled for a terminally ill patient must be filled within how many days or months after it is written according to recent California law?
  - a. Must be filled within 7 days after written.
  - b. Must be filled within 14 days after written.
  - c. Must be filled within 30 days after written.
  - d. Must be filled within 60 days after written.
  - e. Must be filled within 6 months after written.
131. A new prescription for a Schedule III, IV, or V controlled substance that has the following "sig" or directions, "*Take One Tablet PRN,*" with 5 refills, may be filled as written without contacting the prescriber?
  - a. True
  - b. False

132. If a security prescription form comes to your pharmacy for a Schedule II controlled substance and there is an error noted on it you must:
- Not fill the prescription and return it back to the prescriber to rewrite a ne prescription before filling it.
  - Not fill the prescription until you can contact the prescriber for clarification or correction of the error, then you can make the change on the prescription along with documenting the fact that you contacted the prescriber to correct the error. After this is done, you can then fill the prescription as corrected without being required to get a new prescription from the prescriber or a second signature from the prescriber on the remedied prescription.
  - Not fill the prescription until you can contact the prescriber for clarification or correction of the error, and after making the necessary correction of the error, send the prescription to the prescriber for a second signature giving evidence that the prescriber has acknowledged the error that has been corrected. Then the prescription may be filled once you have the second signature.
  - Not fill the prescription until you can contact the prescriber for clarification or correction of the error. Once this is done you may fill the prescription for the patient, but you will need a second signature within 7 days from the prescriber showing that he or she acknowledged the error and the change to correct the incorrect or missing information.
133. A Naturopathic Doctor (ND) may do all of the following except:
- Work with a licensed physician under a protocol.
  - Independently (not pursuant to a licensed physician's protocol) furnish epinephrine to treat anaphylaxis in a patient.
  - Apply and qualify to receive a DEA registration number so the ND can furnish controlled substances (IIIs, IVs and Vs only) pursuant to a physician authorized protocol.
  - Independently (not pursuant to a licensed physician's protocol) furnish Thyroid Tablets to a patient.
  - Independently (not pursuant to a licensed physician's protocol) furnish testosterone tablets to a patient.



134. Which statement is the most incorrect regarding a pharmacy establishing an Emergency Oral Contraception Program?
  - a. The pharmacist must have at least one hour of training in this area through an educational program that is both a recognized provider of this form of training.
  - b. The pharmacy may charge up to a \$25.00 administrative fee for providing this service along with the usual and customary costs of the medication.
  - c. While there are a variety of oral contraceptives that may be used for the emergency oral contraceptive program, if two tablets are used they may be given at the same time within 120 hours of the unprotected sex.
  - d. A statewide protocol that has been approved by the California Medical Board and the California Pharmacy Board may be followed without having any special prescriber involved to sign-off on the program as being the supervising physician.
  
135. The California Board of Pharmacy defines at a minimum that a pharmacy is no longer operational and is considered to be closed if:
  - a. It is not engaged in ordinary activity for at least two days a week during any 180 day period.
  - b. It is not engaged in ordinary activity for at least three days a week during any 60 day period.
  - c. It is not engaged in ordinary activity for at least one day a week during any 120 day period.
  - d. It is not engaged in ordinary activity for at least one day a week during any 30 day period.
  - e. It is not engaged in ordinary activity for at least one-half day a week during any 90 day period.
  
136. The drug *Pregabalin* (*Lyrica*®) used in the management of peripheral neuropathy and postherpetic neuralgia:
  - a. Is categorized as a Schedule II controlled substance.
  - b. Is categorized as a Schedule III controlled substance.
  - c. Is categorized as a Schedule IV controlled substance.
  - d. Is categorized as a Schedule V controlled substance.
  - e. Is not categorized as a controlled substance.

137. Which one of the following is least correct regarding the faxing of prescriptions into a pharmacy?
- a. If a prescription for a non-scheduled drug is faxed to the pharmacy from the prescriber's office, the facsimile may be used as the hard copy and incorporated into the pharmacy's hard copy prescription files.
  - b. If a patient faxes in a new prescription from his or her home to the pharmacy, the pharmacy may prepare the prescription, but cannot dispense it until the pharmacy receives the original prescription from the patient.
  - c. If one independent pharmacy faxes a prescription to another independent pharmacy, the receiving pharmacy may use the facsimile faxed from the sending pharmacy as its hard copy to be incorporated into the receiving pharmacy's hard copy files.
  - d. If a patient wants a prescription that has refills transferred from one independent pharmacy to another, the sending pharmacy may either fax the prescription or phone it into the receiving pharmacy. The receiving pharmacy must have the name and address of the sending pharmacy, the name of the pharmacist or intern faxing or calling in the prescription, all of the prescription information including number of remaining refills, the date the prescription was originally written and the date the prescription was last refilled, and if it is a Schedule III, IV, or V drug, the DEA number of the sending pharmacy. The faxed prescription should then be transferred in writing onto the pharmacy's prescription blanks.
  - e. A prescription for a Schedule III, IV, or V controlled substance that has refills may only be transferred by fax or phone one time to another independent pharmacy to be filled.
138. Which one of the following time periods for maintaining various pharmacy-related records in California is incorrect.
- a. A prescription record from a clinic must be kept for 3 years by the clinic pharmacy.
  - b. A Quality Assurance Medication Error Report must be kept for one year by a pharmacy.
  - c. A pharmacy Self-Assessment Reporting Record must be kept by the pharmacy for 3 years.
  - d. A HIPAA Notice Record signed by the patient must be kept by the pharmacy for 6 years.
  - e. A filled-out Controlled Substance Inventory Record required by the federal government must be kept for 2 yrs.

139. Which one of the following warning labels is not required by law, but is a manufacturer's requirement to provide as a warning?
- A drug that has a central nervous system suppressing effect and may cause drowsiness.
  - A drug that may cause blurring of the vision.
  - A drug that may cause a severe reaction as a result of its interaction with alcohol.
  - A "must refrigerate" label for a drug like insulin.
  - A drug that is a controlled substance that requires an auxiliary label that requires that the patient not give the drug to any other person, and may only be used by the party the drug was prescribed for.
140. A patient comes in with a new prescription for *Coumadin 5 mg.* All you have in stock is a generic of the drug as *warfarin 5 mg.* As a result, which one of following is the more correct answer?
- Since the physician wrote for *Coumadin 5 mg.* you are obligated to give to the patient exactly what the physician ordered; otherwise, you are obligated according to the law to call the physician and ask if it is okay to substitute with a generic for the trade named drug on the prescription.
  - You may substitute the generic *warfarin 5 mg.* for the *Coumadin 5 mg.* without communicating that you are making the substitution to the patient or the physician since it is a generic equivalent, and that you will be charging the patient less compared to the cost for a prescription of *Coumadin 5 mg.*
  - You may substitute provided that you are given permission to do so by the patient, and after you have explained to the patient it will cost them less for the generic. You do not have to contact the prescriber to ask his or her permission to change to the generic.
  - Since *warfarin* has a narrow therapeutic index, you are required under the law to use the same product on all subsequent refills whether you dispense the *Coumadin* or a generic substitute.

141. A patient brings in a refill prescription for Vasotec 10 mg, #60; One tablet daily. The patient has gotten this prescription for the last year. The patient's physician who wrote the prescription for the Vasotec eight months ago with "prn" refills died two weeks ago. As a result which one of the following answers is most correct?
- a. If you do not know the patient's doctor died, you may continue refilling the prescription until you find out about his death.
  - b. If you do not know the patient's doctor died, you are still obligated under the law not to refill the medication since it is your responsibility to find out if the doctor is still alive.
  - c. If you know that the patient's doctor has died, you may not fill the prescription.
  - d. If you know that the patient's doctor has died, you may fill the prescription for at least one more refill, instructing the patient that they must make arrangements with a new physician to write for future prescriptions for this drug.
  - e. If you know that the patient's doctor has died, you may still refill the prescription up to one year from the date it was written.
142. Which one of the following statements is the most correct?
- a. A pharmacist-in-charge (PIC) may serve as a PIC of two pharmacies as long as the second pharmacy is no more than 100 driving miles from the first pharmacy.
  - b. A PIC of one pharmacy may not refuse serving as a PIC at a second pharmacy if the owner or corporation executives of both pharmacies require that arrangement since the law encourages such practices.
  - c. A PIC can only serve as a PIC at one pharmacy, and is not allowed under the law to serve concurrently as a PIC at a second pharmacy.
  - d. There is no limit in the law regarding how many pharmacies a PIC can serve as PIC concurrently.
  - e. A pharmacist cannot serve concurrently as a PIC if he or she also serves as an exemptee-in-charge (presently also referred to as "representative-in-charge") for a veterinary drug-food retailer at another site.

143. Concerning pharmacy technicians checking the work of other pharmacy technicians:
- It is allowed to be done in any hospital or community pharmacy setting as long as there is a policy and procedure for that hospital or community pharmacy allowing a pharmacy technician to check the work of another pharmacy technician.
  - The drug orders do not have to be originally approved by the supervising pharmacist before the pharmacy tech checks the work of the other pharmacy tech.
  - Pharmacy tech checking the work of other pharmacy techs cannot be operational in every hospital or community pharmacy program; it may only occur in acute hospitals that have an ongoing clinical pharmacy program where pharmacists are in the patient care areas.
  - Before a pharmacy tech check pharmacy tech program can be instituted, the California State Board of Pharmacy must issue a special license that allows the pharmacy operation to provide this type of program.
  - The pharmacy tech check pharmacy tech program has not been approved by either the State legislature or the California State Board of Pharmacy as of this date; therefore to have such a program in operation at present is illegal.
144. Which one of the following statements is most correct in the provision of Emergency Oral Contraceptive Therapy according to Plan B sold over-the-counter.
- Several forms of oral contraceptives having different estrogenic and/or progestational components may be used under Plan B.
  - Under "Plan B" the emergency contraceptive agent can only be sold at pharmacies and must be kept behind the pharmacy counter.
  - The person for whom the emergency contraceptive agent is for does not need to be 17 years or older.
  - The pharmacy may charge a \$10.00 administrative fee for selling the Plan B emergency oral contraceptive to the requesting consumer.
  - The consumer purchasing the Plan B emergency oral contraceptive may only purchase one package of the product each time. No more than one package of the EC Plan B may be sold at the time of sale.



**145. Which one of the following is most correct:**

- a. If a Board licensed pharmacy technician that works for you admits to you that he has a drug problem (using Valium without a prescription), but tells you he is not using it anymore, and promises he will not use it again in this illegal manner, you as a pharmacist-in-charge must report this action to the Board of Pharmacy within 14 days of being told this information, as well as consider terminating his employment.**
- b. If a Board licensed pharmacy technician that works for you admits to you that he has a drug problem (using Valium without a prescription), but tells you he is not using it anymore, and promises he will not use it again in this illegal manner, you need not report the incident to the Board but must fire this pharmacy technician on the spot.**
- c. If a Board licensed pharmacy technician that works for you admits to you that he has a drug problem (using Valium without a prescription), but tells you he is not using it anymore, and promises he will not use it again in this illegal manner, based upon the fact that the pharmacy technician openly admitted taking the drug, but promises not to do it again, you are allowed to give him one more chance without firing him or reporting him to the Board. On a second occurrence you must report the pharmacy tech to the Board.**
- d. If a Board licensed pharmacy technician that works for you admits to you that he has a drug problem (using Valium without a prescription), but tells you he is not using it anymore, and promises he will not use it again in this illegal manner, you are required to suspend the pharmacy tech, without reporting him to the Board, for a 90-day period to ensure that he seeks rehabilitation through a special impairment training program. If he succeeds to be rehabilitated through the program, you may bring him back as a pharmacy tech, and again without any report of his circumstance to the Board of Pharmacy.**

146. A patient comes into your pharmacy to get a prescription filled for Neurontin (gabapentin) 600 mg tablets #50 that has the directions, *"take one half tablet as directed for pain."* It is written on a regular prescription blank (a non-security prescription form). In consideration of the requirement of law which one of the following is the most appropriate and correct given each of the noted circumstances below?
- Even though you have the drug in your stock, tell the patient you cannot fill the prescription since the drug ordered is not written for on a special non-security prescription form.
  - Tell the patient you cannot fill the prescription because the method of taking the medication, "one-half tablet as directed for pain," is not spelled-out sufficiently and requires clarification from the prescriber on how to precisely take it (e.g. one-half tablet every 8 hours for pain).
  - Tell the patient you cannot fill the prescription since the FDA has not approved this drug for any form of pain control.
  - You may fill and dispense the order as written.
147. Which statement is most correct regarding the use of Automated Drug Delivery System (ADDS) devices in a community pharmacy?
- In order to have an ADDS device in a pharmacy, it requires a waiver from the State Board of Pharmacy.
  - Records for the ADDS device must be kept for 2 years.
  - Patients wanting to have access to the ADDS device do not have to sign a consent form, they just need to verbally ask for this service.
  - The ADDS device can be used for both new prescriptions and refill prescriptions.
  - The pharmacy portion of a store does not have to be open in order for the patient to have access to the ADDS device that is in the proximity to the pharmacy area.

**148. Which statement is correct regarding the sale of pseudoephedrine over-the-counter?**

- a. The consumer can only purchase 3 packages or up to 9 grams of pseudoephedrine at each purchase transaction.
- b. The law does not apply to a single purchases of one 60 mg pseudoephedrine unit dose package or two 30 mg unit dose packages of pseudoephedrine.
- c. Pseudoephedrine in the liquid form including pediatric liquids may be sold in any amounts since they are not subject to the ruling that only applies to tablet or capsule formulations of the pseudoephedrine product.
- d. Pseudoephedrine products can still be displayed on pharmacy shelves and do not have to be kept in a locked cabinet or behind the pharmacy counter.
- e. The customer does not have to sign a special log book upon purchasing a pseudoephedrine product.

**149. Based upon California State and federal law a pharmacist in California may fill a legitimate non-scheduled drug prescription written by a physician from which of the following jurisdictions?**

- I.            Guam
- II.          Canada
- III.        Virgin Islands

- a. I only
- b. II only
- c. I and III only
- d. II and III only
- e. None of the above

**150. When prescription drugs are delivered to a pharmacy, after the pharmacy orders them from a drug wholesaler, who may sign for the receipt of those delivered drugs?**

- I.            Pharmacist
- II.          Pharmacist Intern
- III.        Pharmacy Technician
- IV.        Pharmacy Clerk

- a. I only
- b. I and II only
- c. I, II, and III only
- d. I, II, III, and IV

151. The Attorney General's ruling that a prescription for a non-scheduled drug with "prn" refills may only be refilled for up to one year is a(an):
- Statute
  - Regulation
  - Opinion
  - Ordinance
  - Black Letter Law
152. Regarding the keeping of prescription records at an off-site facility, if those prescription records are controlled substance prescription records:
- You may place those controlled substance prescription records in the off-site facility after one year from the date a prescription was last dispensed.
  - You may place those controlled substance prescription records in the off-site facility after two years from the date a prescription was last dispensed.
  - You may place those controlled substance prescription records in the off-site facility after three years from the date they are written.
  - You may place those controlled substance prescription records in the off-site facility after five years from the date of last filling that prescription.
  - Because they are controlled substance prescription records they may not be moved to an off-site facility at any time.
153. A patient presents a prescription to be refilled from a prescriber who you as the pharmacist know passed away (died) two weeks ago. The medication is for a 30 day supply of a non-scheduled prescription drug that was originally three months previously with six refills of which two of the refills have already been filled and dispensed, and the third refill is due. Given the fact that the prescriber is no longer alive, which one of the following is allowable based upon law and/or standard of practice, and the need for the patient to have the medicine based upon her medical condition?
- You may refill the prescription for the entire 30 day supply.
  - You may only provide a 24 hour supply of the drug.
  - You may not fill the prescription without getting approval from a living prescriber.

154. Which one of the following does not require by law an auxiliary warning label, but requires a warning label based upon the manufacturer's requirement?
- a. A drug that has a central nervous system suppressing effect and may cause drowsiness.
  - b. A drug that may cause blurring of the vision.
  - c. A drug that may cause a severe reaction as a result of its interaction with alcohol.
  - d. A "must refrigerate" label for a drug like insulin.
  - e. A drug that is a controlled substance that requires an auxiliary label that requires that the patient not give the drug to any other person, and may only be used by the party the drug was prescribed for.
155. Regarding the Quality Assurance Program and issues with attempting to minimize medication errors, which one of the following is the least correct?
- a. If a medication error does occur, the pharmacy is required to prepare a medication error report within 48 hours or two business days once the error is discovered.
  - b. A medication error can be attributed to a patient receiving the correct drug, but not getting the prescribed drug within a reasonable period of time.
  - c. The pharmacy in preparing the medication error report does not need to place the specific name of the employee that may have caused the error on the report, but just needs to note the employee's job title and write, as an example, "that the wrong drug was dispensed to Ms. Jones by a pharmacy technician, that belonged to another Ms. Jones."
  - d. The pharmacy must forward to the Calif. State Board of Pharmacy a copy of the written-up medication error report within 30 days of the error either occurring or being first noticed.
  - e. The pharmacy must keep the medication error report on file at the pharmacy for at least one year after the error occurred.



**156. Which statement is most correct when selling hypodermic syringes and needles?**

- a. They may be sold over-the-counter to anyone who is purchasing insulin as long as the purchaser shows proof of using insulin and signs a hypodermic syringe/needle log or registry book.**
- b. Only up to 10 syringes and needles may be sold over-the-counter if the person is a diabetic and fills in the information and signs the hypodermic syringe/needle log or registry book.**
- c. If the use is for veterinary purposes, a prescription for the needed syringes and needles must be issued by the licensed veterinarian, and the purchaser must fill in the information and sign the hypodermic syringe/needle log or registry book.**
- d. Up to 10 syringes and needles can be sold over-the-counter to a customer, even if that customer is unknown to the pharmacist, and no explanation needs to be given for the intended use by the customer, nor are they required to fill-in information or sign a log or registry book.**
- e. The customer who is known to the pharmacist, and who has prescriptions filled for needles and syringes in the past for a legitimate medical need may receive syringes and needles over-the-counter if there is an emergency need for the needles and syringes. No log or registry book need be filled-in or signed for such a purchase.**

**157. Medications that require refrigeration (not at freezing temperatures) shall be maintained at Centigrade that range from:**

- a. 1.0° C to 5.5° C.**
- b. 2.2° C to 7.7° C.**
- c. 5.3° C to 10.4° C.**
- d. 8.4° C to 15.6° C.**
- e. 18.7° C to 25.3° C.**

158. Which one of the ratios is most correct regarding a single pharmacist working with the following ancillary pharmacy personnel in a community pharmacy setting?
- a. That a single pharmacist may have up to two pharmacy technicians working with him or her.
  - b. That a single pharmacist may have up to two pharmacist interns working with him or her.
  - c. That a single pharmacist may have only one pharmacist intern working with him or her.
  - d. That a single pharmacist may only have up to two pharmacy clerks working with him or her.
159. You receive a prescription to be filled, written by a California licensed optometrist who is authorized by the California Optometry Board to write prescriptions and has a DEA registration number. The prescription is for hydrocodone and acetaminophen in combination (Vicodin) for the treatment of a scratched cornea. Which one of the following is the most correct answer?
- a. The pharmacist may not fill this prescription even if the optometrist has a DEA number since it is not within the scope of this practitioner's practice.
  - b. The pharmacist may not fill this prescription unless the optometrist is working under the supervision of a physician who has developed a protocol authorizing the optometrist to write for this prescription medication.
  - c. The pharmacist may only fill this prescription if the amount of the hydrocodone in combination with acetaminophen does not exceed a three day supply, and does not require that this medication be only written for under the supervision of a physician's directed protocol.
  - d. The pharmacist may fill up to a twenty-one day supply of the hydrocodone in combination with the acetaminophen tablets, and does not require that this medication be only written for under the supervision of a physician's directed protocol.
  - e. The optometrist may write for any amount of this drug without restriction since the condition is within the scope of the optometrist's practice, and he or she has a valid DEA registration number.

160. Once it is discovered that a licensed pharmacy technician was stealing prescription drugs from the pharmacy, it is the PIC's responsibility to report that theft once discovered, within what number of days to the State Board of Pharmacy?
- Within 5 days.
  - Within 10 days.
  - Within 14 days.
  - Within 21 days.
  - Within 30 days.
161. Which one of the following is the more correct answer regarding the dispensing of *Suboxone®* (*buprenorphine with Naloxone*) by a pharmacy pursuant to a prescription written by a physician for the treatment of an narcotic addiction?
- The drug may be dispensed by a pharmacy for treating addiction that is the result of any controlled substance within any of the Schedules.
  - The drug may be used to treat patients who have an addiction to a Schedule III controlled substance only.
  - The drug may only be used to treat addictions attributed to Schedule III, IV, or V controlled substances, but may not be used to treat addictions to Schedule II controlled substances.
  - The drug may only be prescribed by physicians who are registered with the State of California, and have taken 30 hours of course material related to pain management.
  - No physician under any circumstance may prescribe this drug for the exclusive purpose of treating addiction, even if they are registered with the State of California to treat addiction, and are specifically trained in the management of pain as well.
162. Recently the drug substance dextromethorphan was:
- Restricted in only selling to persons 18 years or older.
  - Only allowed to be sold in pharmacies and kept in the pharmacy behind the counter.
  - Requiring that the purchaser sign for it in a government issued log book.
  - Restricted in being sold to customers in supplies of more than one package of any drug product containing dextromethorphan.

163. A physician calls in a non-scheduled drug prescription for a patient that is taking it for the first time. The physician indicates that he wants the prescription delivered to the patient's home per the request of the patient. You prepare the prescription, and have it delivered to the patient's home. As part of your responsibility to this patient regarding compliance with the consultation requirements of the State of California, you are obligated to do which one of the following?
- a. It is contrary to the law to deliver a new prescription to a patient. It is required that the patient, or a representative of the patient, come to the pharmacy to pick the prescription up so that the patient, or representative of the patient can be properly counseled on the use of the new medication.
  - b. The new prescription can be delivered, but the pharmacist must call the patient by phone to provide a consultation orally before the medication is delivered.
  - c. The new prescription can be delivered, but the pharmacist must call the patient by phone to provide a consultation after the medication has been delivered.
  - d. The new prescription can be delivered, but must have the new prescription accompanied with mandatory written information about important items the patient needs to know about the new medication they are to take.
  - e. The new prescription can be delivered, but the patient must receive a written statement that if they have any questions about their new medication, they are to telephone the pharmacy to talk with a pharmacist. The pharmacy may also send written information about important items the patient needs to know about the new medication they are to take.
164. Which one of the following time periods required to maintain various pharmacy-related records in California before disposing of them, is incorrect?
- a. Clinic pharmacy records must be kept for 3 years from date of last entry.
  - b. Community pharmacy prescription records must be kept for 3 years from date of last entry.
  - c. The Controlled Substance Inventory Record must be kept for 2 years after it is completed.
  - d. A filled-out DEA Form 222 Record must be kept for 3 years.
  - e. A Quality Assurance Medication Error Report must be kept for 1 year.

165. Pharmacies that act exclusively as Internet Pharmacies, must be registered with the:
- California Board of Pharmacy
  - D.E.A.
  - F.D.A.
  - California Department Public Health
  - F.B.I.
166. A physician licensed in Arizona and having a DEA registration number wishes to order a prescription for Tylenol with Codeine 1 grain (a Schedule III controlled substance) for a California patient. Which one of the following is the most correct regarding the Arizona physician's ability to order this prescription for a California residence?
- The Arizona physician, because he or she is out-of-state is allowed to write the prescription on a regular prescription blank (not a security form prescription), and the California pharmacy can honor this prescription for a California resident.
  - The out-of-state physician can call the prescription in to a California pharmacy allowing the pharmacist to place the called-in prescription on a regular prescription blank used in the pharmacy. However, the out-of-state physician cannot be allowed to authorize up to 5 refills, he or she may only order the prescription for one time use only.
  - The out-of-state physician can call the prescription into a California pharmacy along with refills allowing the pharmacist to place the called-in prescription on a regular prescription blank used in the pharmacy, and the pharmacy is allowed to fill the prescription just as it would for a California licensed prescriber.
  - The out-of-state physician can only write for Schedule IV and V controlled substances (along with the maximum refill allowance) for a California resident. He or she cannot write for or call into a California pharmacy prescriptions for IIs or IIIs.
  - The out-of-state physician cannot write for or call into a California Pharmacy any controlled substance prescriptions because he or she is not licensed as a prescriber in the State of California.



167. Which one of the following statements is incorrect regarding the transferring of prescriptions between pharmacies?
- a. A pharmacy clerk can transfer information regarding a prescription to be filled at another pharmacy, but only the pharmacist at the receiving pharmacy may record the information being transmitted from the sending pharmacy by the clerk.
  - b. The receiving pharmacy must take all the remaining refills left on the prescription being transferred, while the sending pharmacy must cancel the prescription from being refilled once transferred.
  - c. Nonscheduled drug prescriptions may be transferred to different pharmacies as many times as there are refills.
  - d. Schedule III, IV, and V controlled substance prescriptions with refills may be transferred to another pharmacy only one time.
  - e. The receiving pharmacy for a transferred prescription with refills must record, among other things, the date the prescription was originally written, and the date of the last refill.
168. A patient comes in for a refill on her Schedule III Tylenol with codeine 1 grain tablets # 20. The prescription originally had five refills (20 tablets each) that have all been filled. The prescription was originally written in March 2012, and she now comes in on May 1, 2012 to get the prescription refilled. In the process of acquiring additional refills on the prescription, which one of the following is procedurally correct based upon the law?
- a. A clerk can call the prescriber's office to acquire the refill and if a continuance of the prescription is approved for an additional 5 refills, that information can be made note of on the original prescription and then filled.
  - b. A pharmacy technician can call the prescriber's office to acquire the refill and if a continuance of the prescription is approved for an additional 5 refills, that information is to be transcribed by the pharmacy technician on a new prescription blank in the pharmacy.
  - c. Only a pharmacist or pharmacist intern can call the prescriber's office to acquire the refill approval and if a continuance of the prescription is approved for an additional 5 refills, that information can be made note of on the original prescription and then filled.
  - d. Only a pharmacist or a pharmacist intern can call the prescriber's office to acquire the refill approval and if a continuance of the prescription is approved for an additional 5 refills, that information is to be transcribed by the pharmacist or the pharmacist intern on a new prescription blank in the pharmacy.

169. If a pharmacist in California desires to have his or her license placed on an "inactive" status which one of the following is most correct?
- That pharmacist can practice a minimum of only 10 hours per week.
  - If one's pharmacist license is placed on "inactive" status, the license must be reinstated to "active" license status immediately after one year; otherwise the license is placed on a "retired" license status.
  - During "inactive" pharmacist license status, the "inactive" pharmacist must still take the usual required hours of accredited C.E. courses in order to eventually reinstate their license back to an "active" status.
  - If a pharmacist with "inactive" license status wishes to reinstate their license at some future date, they will be required to retake and pass the NAPLEX and the California Pharmacy Practice Standards/Jurisprudence Examination again.
  - A pharmacist with an "inactive" license may acquire "active" license status by notifying the Board of Pharmacy of the desire to renew their license, and must show proof of satisfying the necessary C.E. requirements mandated by the Board in order to achieve the reinstatement of an "active" license. Reinstating an "inactive" license to "active" does not require the retaking of the NAPLEX and/or the California Pharmacy Practice Standards/Jurisprudence Examination.

170. There are four hospitals that are owned by a single corporation. In regards to servicing the compounding needs and preparation of extemporaneous unit dose packaging for patients, which one of the following below is the most correct?
- a. A California centralized hospital pharmacy may do the compounding and preparation of extemporaneous unit dose packaging for all four hospitals even if the other hospitals are in the eastern part of the United States.
  - b. A centralized hospital pharmacy in Los Angeles may do the compounding and preparation of extemporaneous unit dose packaging for any of the other owned hospital pharmacies if located in other areas of California.
  - c. A centralized hospital pharmacy in California may do the compounding and preparation of extemporaneous unit dose packaging for any of the other owned hospital pharmacies if located within a 100 mile radius of one another, and the extemporaneous unit doses prepared do not have to have barcoding.
  - d. A centralized hospital pharmacy in California may do the compounding and preparation of extemporaneous unit dose packaging for any of the other owned hospital pharmacies if located within a 75 mile radius of one another, and the extemporaneous unit doses prepared must have barcoding to be used for the checking of accuracy during the medication administration at the patient's bedside.
  - e. A centralized hospital pharmacy may not engage in the compounding or preparation of extemporaneous unit doses for patients in its other owned hospitals.



# ANSWER SHEET

1. a b c d e ☐ ☐ ☐ ☐ ☐ 19. a b c d e ☐ ☐ ☐ ☐ ☐ 37. a b c d e ☐ ☐ ☐ ☐ ☐ 55. a b c d e ☐ ☐ ☐ ☐ ☐ 73. a b c d e ☐ ☐ ☐ ☐ ☐
2. a b c d e ☐ ☐ ☐ ☐ ☐ 20. a b c d e ☐ ☐ ☐ ☐ ☐ 38. a b c d e ☐ ☐ ☐ ☐ ☐ 56. a b c d e ☐ ☐ ☐ ☐ ☐ 74. a b c d e ☐ ☐ ☐ ☐ ☐
3. a b c d e ☐ ☐ ☐ ☐ ☐ 21. a b c d e ☐ ☐ ☐ ☐ ☐ 39. a b c d e ☐ ☐ ☐ ☐ ☐ 57. a b c d e ☐ ☐ ☐ ☐ ☐ 75. a b c d e ☐ ☐ ☐ ☐ ☐
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7. a b c d e ☐ ☐ ☐ ☐ ☐ 25. a b c d e ☐ ☐ ☐ ☐ ☐ 43. a b c d e ☐ ☐ ☐ ☐ ☐ 61. a b c d e ☐ ☐ ☐ ☐ ☐ 79. a b c d e ☐ ☐ ☐ ☐ ☐
8. a b c d e ☐ ☐ ☐ ☐ ☐ 26. a b c d e ☐ ☐ ☐ ☐ ☐ 44. a b c d e ☐ ☐ ☐ ☐ ☐ 62. a b c d e ☐ ☐ ☐ ☐ ☐ 80. a b c d e ☐ ☐ ☐ ☐ ☐
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13. a b c d e ☐ ☐ ☐ ☐ ☐ 31. a b c d e ☐ ☐ ☐ ☐ ☐ 49. a b c d e ☐ ☐ ☐ ☐ ☐ 67. a b c d e ☐ ☐ ☐ ☐ ☐ 85. a b c d e ☐ ☐ ☐ ☐ ☐
14. a b c d e ☐ ☐ ☐ ☐ ☐ 32. a b c d e ☐ ☐ ☐ ☐ ☐ 50. a b c d e ☐ ☐ ☐ ☐ ☐ 68. a b c d e ☐ ☐ ☐ ☐ ☐ 86. a b c d e ☐ ☐ ☐ ☐ ☐
15. a b c d e ☐ ☐ ☐ ☐ ☐ 33. a b c d e ☐ ☐ ☐ ☐ ☐ 51. a b c d e ☐ ☐ ☐ ☐ ☐ 69. a b c d e ☐ ☐ ☐ ☐ ☐ 87. a b c d e ☐ ☐ ☐ ☐ ☐
16. a b c d e ☐ ☐ ☐ ☐ ☐ 34. a b c d e ☐ ☐ ☐ ☐ ☐ 52. a b c d e ☐ ☐ ☐ ☐ ☐ 70. a b c d e ☐ ☐ ☐ ☐ ☐ 88. a b c d e ☐ ☐ ☐ ☐ ☐
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18. a b c d e ☐ ☐ ☐ ☐ ☐ 36. a b c d e ☐ ☐ ☐ ☐ ☐ 54. a b c d e ☐ ☐ ☐ ☐ ☐ 72. a b c d e ☐ ☐ ☐ ☐ ☐ 90. a b c d e ☐ ☐ ☐ ☐ ☐





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# ANSWER SHEET

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| 1.  | a b c d e | 19. a b c d e | 37. a b c d e | 55. a b c d e | 73. a b c d e |
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| 3.  | a b c d e | 21. a b c d e | 39. a b c d e | 57. a b c d e | 75. a b c d e |
| 4.  | a b c d e | 22. a b c d e | 40. a b c d e | 58. a b c d e | 76. a b c d e |
| 5.  | a b c d e | 23. a b c d e | 41. a b c d e | 59. a b c d e | 77. a b c d e |
| 6.  | a b c d e | 24. a b c d e | 42. a b c d e | 60. a b c d e | 78. a b c d e |
| 7.  | a b c d e | 25. a b c d e | 43. a b c d e | 61. a b c d e | 79. a b c d e |
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| 9.  | a b c d e | 27. a b c d e | 45. a b c d e | 63. a b c d e | 81. a b c d e |
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| 16. | a b c d e | 34. a b c d e | 52. a b c d e | 70. a b c d e | 88. a b c d e |
| 17. | a b c d e | 35. a b c d e | 53. a b c d e | 71. a b c d e | 89. a b c d e |
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## ANSWER SHEET

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## ***ANSWERS TO PHARMACY LAW QUESTIONS***

1. **[d] is the more correct answer.**

When nonscheduled prescription drugs are lent, borrowed, sold, or bought between pharmacies, it is the responsibility of both sides to the transaction to record in a log book what is lent, borrowed, sold or bought. The record should show the item transacted, its strength, the amount, the date, who made the transaction, and whether lent, borrowed, sold, or bought. This is also the case for Schedule III, IV, and V controlled substances. Schedule II controlled substances may only be transferred using a DEA Form 222.

Section 4081[a] of the Calif. Bus. & Prof. Codes states, "All records of manufacturer and of sale, purchase or disposition of dangerous drugs or devices shall be at all times, during business hours, open to inspection by authorized officers of the law, and shall be preserved for at least 3 years from the date of making."

2. **[b] is the correct answer.**

When Schedule II drugs are transferred between pharmacies, a special DEA Form 222 (a triplicate form) is required. This is according to the federal codes (21 CFR 1305.03-1305.16).

3. **[d] is the correct answer.**

According to Section 1705 of Title 16, Calif. Code of Regulations, "A pharmacy... who files a petition in bankruptcy, or who has a receiver appointed, or who enters into any liquidation... shall notify the Board immediately in writing of such fact, and shall set forth the following information, if known: a) Date of sale or transfer of drugs and/or devices, b) Name and address of purchaser,

c) Inventory of dangerous drugs and devices showing their disposition, and location of records of sale, purchase, and disposition of dangerous drugs and devices.” Answers [a], [b], [c] and [e] all require a written notice to the Board of Pharmacy within 30 days.

4. [b] is the best answer.

While it is perfectly all right for a pharmacist, or an employee of the pharmacy to deliver a prescription to a patient's home or office (see Section 1713[b] of Title 16, Calif. Code of Regulations), there is an issue of whether or not confidentiality is breached by providing the prescription to an non-designated party. Here, the prescription was to go to the home of Mrs. Jones and be provided to her 15 year old son as per the instructions of Mrs. Jones. By giving the prescription to a party not designated by Mrs. Jones, is a violation of Section 1764 of Title 16, Calif. Code of Regulations which reads, “No pharmacist shall exhibit, discuss, or reveal the contents of any prescription...with any person other than the patient or his or her authorized representative, the prescriber or other licensed practitioner then caring for the patient, another licensed pharmacist serving the patient, or a person duly authorized by law to receive such information.” As to the issue of whether this is or is not in the best interest of the patient, since the delivery of the drug did not appear to be an emergency, to simply give it to an unauthorized party because of convenience would not appear to be in the patient's best interest; especially when a matter such as this one is to be held in strict confidence as required by law.

5. [a] is the correct answer.

Section 4122[e][1] of the Calif. Bus. & Prof. Codes states, “...No pharmacy shall be required to... provide the price of any controlled substance in response to a telephone request.” Section 4122 of the codes addresses and allows for the other conditions noted (See *b* through *e* of Section 4122).

6. [c] is the correct answer.

Section 11056[g] of the Calif. Health & Safety Codes assigns *ketamine* either by itself or in mixture to the category of Schedule III of the controlled substances. Federally, *ketamine* in 2001 was changed from a nonscheduled drug to Schedule III status. Therefore, the drug is now classified as a Schedule III controlled substance both federally and in California.

7. [d] is the correct answer.

Section 4111[a][3] of the Calif. Bus. & Prof. Codes disallows a registered prescriber in California to own more than 10 percent of a community pharmacy operation. If such ownership is to exist, the ownership must be vested in a corporation business structure. If there are more than two licensed prescribers they collectively may own only 10% of the shares in any proportion desired. This rule does not apply under the Knox-Keene Health Care Service Plan Act of 1975 to certain non-profit institutions, HMOs, or hospital pharmacy outpatient facilities that may be exclusively owned by California licensed prescribers.

8. [a] is the correct answer.

Calif. Bus. & Prof. Code, Sec. 4170[c] states, "Prescriber means a person, who holds a physician's or surgeon's certificate, or a license to practice osteopathic medicine, optometry, naturopathic medicine, dentistry, veterinary medicine, or podiatry." Psychiatry is a specialty of medicine and thus a psychiatrist is allowed to prescribe prescription drugs, whereas psychology is not a specialty of medicine.

9. [b] is the correct answer.

According to Section 4333[a] of the Calif. Bus. & Prof. Codes, "All prescriptions filled shall be kept on file... for a period of at least 3 years..." This 3 year period commences after the prescription is last filled.

10. **[b] is the best answer.**

Based on Section 4040[a][2] of the Calif. Bus. & Prof. Codes that states, regarding the issuance of a prescription, that a prescription may only be “issued by a physician, dentist, optometrist, podiatrist or veterinarian licensed in this state,” hopefully will make the answer to this question obvious. Here we have the pharmacist prescribing prescription drugs based upon the request of this patient. The fact of whether or not the dentist is known well by the pharmacist still does not give the pharmacist a license to prescribe prescription drugs. Because the action by the pharmacist is a blatant violation of the law, this in itself will almost always prevent the pharmacist’s action from being in the best interest of the patient.

11. **[a] the more correct answer.**

This question attempts to test your knowledge concerning the “drug diversion laws.” Generally, according to Section 4380 of the Calif. Bus. & Prof. Codes, “The resale... of drugs acquired at preferentially low prices... is prohibited except...: 1) when sold to a walk-in customer pursuant to a prescription, provided that those sales represent less than 1 percent of the drugs purchased by the seller for its own use in the state, and 2) in the occasional emergency situation where no other sources are readily available in the community to meet the emergency need.” If a prescription drug is borrowed from a non-profit pharmacy operation by a for-profit pharmacy operation, the following should be taken into account:

- The for-profit pharmacy is out of the drug in the quantity ordered.
- The for-profit pharmacy may only acquire the prescription drug from a non-profit pharmacy for an identifiable patient where there is an immediate need to furnish the drug for the health and welfare of the patient;



- No more than what is needed for the patient's prescription should be acquired from the non-profit pharmacy;
- The drug should only be acquired from the non-profit to be filled by the for-profit pharmacy for a patient who is having a difficult time getting the prescription filled at other pharmacies; and
- The for-profit pharmacy must return the exact drug in the amount originally acquired back to the non-profit pharmacy when the drug comes in from the wholesaler. There may not be any substitute with either another drug product or a generic variation. Also, the drug may not be purchased from the non-profit pharmacy by the for-profit pharmacy – it may only be borrowed. (Only another non-profit pharmacy may purchase the drug from a like non-profit pharmacy, but only to the extent of 1% of the purchasing pharmacy's annual purchases.)

12. [e] is the correct answer.

The law according to Section 1712[b] of Title 16, Calif. Code of Regulations prior to 1997 stated, "The minimum area of the pharmacy, excluding enclosed storerooms (also excludes bathrooms), shall be not less than 240 square feet." This is no longer the case since Section 1712 was repealed in March of 1996. The present law represented by Section 1714[b], under Title 16, does not place a restriction as to the minimum area a pharmacy must occupy before being considered for licensing. 1714[b] reads in pertinent part that, "The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy."

13. [c] is the correct answer.

Section 11056[c][2] of the Calif. Health & Safety Codes places suppository forms of amobarbital, secobarbital, or pentobarbital in a Schedule III category, and not Schedule II designation which would have been the case if these agents were in tablet, oral liquid, capsule, or injectable form.

14. **[C]** would be the better answer.

According to Section 4062 of the Calif. Bus. & Prof. Codes, "A registered pharmacist may in good faith, furnish without a prescription a dangerous drug or device in reasonable quantities without a prescription during a federal, state, or local emergency to further the health and safety of the public." In a state of emergency, if a patient comes into your pharmacy and has never gotten a prescription filled at your pharmacy, you may extend a reasonable supply of both nonscheduled as well as scheduled controlled substances (including Schedule IIs) upon a showing of good evidence that the party is presently taking the drug, and continues to have a medical need for the drug. The drug(s) that you provide the patient in a reasonable quantity (usually 72 hours worth) must be drugs the patient has been receiving, and not necessarily from your pharmacy.

As an example, if a patient brought in a labeled prescription vial from another pharmacy, and the evidence was reasonably clear that it was for that patient and they presently need more of the drug, you could provide an emergency supply of that drug even though you do not have any past prescription record on the patient.

When a pharmacist does furnish a drug under the state of emergency allowance, he or she must keep a log of the following information:

- a. The date, name and address of the person to whom the drug is furnished.
- b. The name, strength and quantity of the drug furnished.
- c. The prescriber's name, address and phone number.

The pharmacist shall communicate with the prescriber as soon as possible to inform him or her about providing the patient with the drug and the amount provided. Although the wording in Section 4062 does not

indicate that a purpose as to why the pharmacist furnished the drug to the patient needs to be stated on the log, documentation of this information should probably be included.

15. [b] is the correct answer.

There is no mention in Section 1717 of Title 16, Calif. Code of Regulations of the requirement to put the price on the prescription. Section 1717[b] specifically notes the items required on the prescription before it is filed away: a) a retrievable method such as a prescription number, b) the date dispensed, c) the name or initials of the dispensing pharmacist, and d) if a generic drug is dispensed, the name of the distributor or manufacturer.

The placement of the price on the face of the prescription is considered an ethical requirement as opposed to a legal one.

16. [d] is the more favorable answer.

No longer is there a requirement that the Hypodermic Needle & Syringe Book be made entry into when a hypodermic needle or syringe is issued based upon Calif. Bus. & Prof. Code 4145[a][1] that states in pertinent part, *"A pharmacist... may, without a prescription, furnish hypodermic needles and syringes for human use... without a prescription if: The person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a needle or syringe to administer a medicine or treatment."* No wording in the law makes it required to enter information into a Hypodermic Needle or Syringe log book since a prescription is otherwise required. Two other exceptions to the prescription requirement also exist, if syringes or needles are required for animal use, or for special city declared disease prevention programs such as AIDS and hepatitis C prevention and where the pharmacy is registered for the Disease Prevention Demonstration Project to give out needles and syringes (maximum of 30) over-the-counter,

and without any patient registration requirement. The recipient must be 18 years or older as one of the requirements for this project.

17. **[b]** is the correct answer.

Title 16, Calif. Code of Regulations 1711[f] only requires that the medication error or review prepared by the pharmacy staff need only be kept as a record for one year. The other four answers *a, c, d* and *e* are all correct regarding the time period the medication profile, federal drug inventory form, the DEA 222 order form copy, and the pharmacy self assessment record must be kept.

18. **[c]** is the correct answer.

The rule regarding a “central fill” pharmacy is that if it prepares prescriptions for other pharmacies, the central fill pharmacy must use its own drug inventory to fill another pharmacy’s submitted prescription and prepare its own label (with the central filling pharmacy’s address) to be affixed to the prescription vial before transferring it back to the pharmacy where the patient originally brought the prescription.

19. **[c]** is the correct answer.

Section 11170 of the Calif. Health & Safety Codes states, “*No person shall prescribe, administer, or furnish a controlled substance for himself.*” However, the law does not appear to prevent a prescriber from prescribing, administering, or furnishing a controlled substance for a family member provided there is a prescriber-patient relationship, the drug is being prescribed for a legitimate medical purpose, and a good faith examination was preformed. Note that the dispensing pharmacist is still responsible for ensuring that the controlled substance prescription is for someone other than the prescribing prescriber, and is for a legitimate medical purpose.

20. [a] is the better answer.

Section 310.515 of Title 21, Code of Federal Regulations requires that the package insert provided by the manufacturer of an estrogenic agent such as *Premarin* be given to the patient at the time of dispensing or administering the drug. The information provided in the package insert is to instruct the patient on risks versus benefits of the drug when taken. Such written instruction allows the patient to make an informed decision as to whether or not to go forward in taking that medication. By not giving the patient package insert on the estrogenic agent used based upon Section 310.515 regardless of what was requested by the prescriber is a violation of the law.

Whether or not the decision of withholding the information from the patient was or was not in the best interest of the patient is a more difficult issue. At the time the decision was made there was a fear that if the patient read the information she may not have taken the medication in fear of developing cancer. Because the physician's concern was about the patient's well being and not to induce any fears in her - probably the better answer is that the action was done with the patient's best interest in mind.

Obviously, if the result of taking the drug would cause a possible cancer, this would not be in the best interest of the patient. Since there is no information about any history of the patient having cancer within the fact pattern, the prescriber's legitimate concerns, and you following those concerns tend to give greater weight to the decision at that moment, and what was done, was done in the best interest of the patient. (IF THIS WAS AN ACTUAL QUESTION ON THE TEST, PROBABLY BOTH [a] AND [b] WOULD BE ACCEPTABLE ANSWERS)



21. **[a]** is the better answer.

Calif. Bus. & Prof. Code, Sec. 4052[a][2] states that only a pharmacist (also includes a pharmacist intern acting under the supervision of a pharmacist) can transfer prescription refills between pharmacies. Thus, a pharmacist must be involved at both the transmitting and at the receiving end of the telephone transfer of the refills and not a pharmacy clerk or pharmacy technician.

22. **[c]** is the correct answer.

CURES Program as of January 1, 2007 requires that Schedule II, III and IV controlled substances be transmitted electronically to the central government information data base on a weekly basis. (See Calif. Health & Safety Code, Section 11165[a][b][d]).

23. **[e]** is the correct answer.

According to Section 11166 of the Calif. Health & Safety Codes, "No person shall fill a prescription for a controlled substance after six months has elapsed from the date written on the prescription by the prescriber." The security prescription was written on January 10, 20xy; therefore, the Schedule II controlled substance ordered must be filled by July 10, 20xy.

24. **[c]** is the correct answer.

The manner in which to determine what the missing number is, is to arbitrarily insert a number and go through the following steps (assume that we use the number "3" as the missing number):

Step 1 - Add all of the odd positioned numbers in the sequence together, except for the last digit.

$$6 + \underline{\text{"3"}} + 8 = 17$$

- b. Step 2 - Add all of the even positioned numbers in the sequence together and multiply the result by 2.

$$3 + 5 + 7 = 15 \times 2 = 30$$

- c. Step 3 - Add the sum of the odd number result from Step 1 to the sum of the even number result from Step 2.

$$17 + 30 = 47$$

Step 4 - The last digit ("7") in the added total from Step 3 should be the same number as the last number in the federal registration number ("7"). If the two numbers are the same, this indicates that the federal registration number is based upon an authentic method of calculation.

Therefore, the number "3" was the correct fill-in number.

25. [C] is the better answer.

The answer to this question is based upon the "General Emergency Refill" statute. Section 11201 of the Calif. Health & Safety Codes states, "A prescription for a controlled substance, except those appearing in Schedule II, may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might present an immediate hazard to the patient's health and welfare or might result in intense suffering. The pharmacist shall refill only with a reasonable amount sufficient to maintain the patient until the prescriber can be contacted." Upon refilling a prescription on an emergency basis with a reasonable amount of drug requires that the pharmacist record the following on the reverse side of the prescription:

- a. The date and quantity of the emergency refill.
- b. Note that the prescriber was not available.
- c. Indicate the basis for the pharmacist's judgment in providing an emergency supply of the drug.

The pharmacist must inform the patient that the prescriber was not available, and why he or she is providing an emergency supply to the patient. The pharmacist must contact the prescriber to inform him or her what was done.

26. **[C]** is the correct answer.

Section 1793.2 of Title 16, Calif. Code of Regulations does not allow the pharmacy technician to orally consult with the prescriber to provide that prescriber with pharmacological information about a drug, even if the technician is reading directly from a reputable source of medical or pharmaceutical literature. According to Section 1793.2 the pharmacy technician is limited to the following nondiscretionary tasks:

- a. Removing the drug or drugs from stock.
- b. Counting, pouring, or mixing pharmaceuticals.
- c. Placing the drug product into a container.
- d. Affixing the label or labels to the container.
- e. Packaging and repackaging.

Calif. Health & Safety Code, Section 11207[b] now "allows a pharmacy technician to compound, prepare, fill or dispense a prescription for a controlled substance when done under the personal supervision of a pharmacist."

27. **[d]** is the correct answer.

Apomorphine has been removed from the Schedule II Controlled Substance list in California and is no longer a Scheduled drug in this State.

28. **[b]** is the correct answer.

Section 4180[a][2] of the Calif. Bus. & Prof. Codes changed in 2006 from a 7 year requirement to a 3 year requirement for a clinic pharmacy in the keeping of records on the amounts of drugs purchased, administered, and dispensed.

29. **[a]** is the correct answer.

Section 1707.1[a][2] states, “The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.”

30. **[d]** is the correct answer.

According to Section 4074[d] of the Calif. Bus. & Prof. Codes when a hospital discharges a patient with medications there shall be a “...written policy to ensure that each patient shall receive information regarding each medication given at the time of discharge. This information shall include the use and storage of each medication, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a physician...”

Regarding the other answers, [a] is wrong because the California regulation on consultation requires that “A pharmacist must provide oral consultation to the patient...” - the pharmacist may not “offer to consult with the patient” which is wording from the *OBRA 90* legislation. To “offer to consult” gives the patient the opportunity to refuse or accept - this cannot be done under California law (see Title 16, Calif. Code of Regulations, Section 1707.2[a]). Answer [b] is wrong because the law makes no provision of allowing written information in lieu of an oral consultation (see Section 1707.2[a]). Answer [c] is wrong even though Section 1707.2[a] does not mention “pharmacist-intern.” A pharmacist-intern is allowed to do most all activities performed by a registered pharmacist, but only under the supervision of a pharmacist. Thus, if a pharmacist-intern is

providing a patient with a consultation on the patient's medications, such consultation must be done within the hearing range of the supervising pharmacist. Answer [e] is also wrong based upon Section 1707.2[b][2] which states, "When the patient or agent is not present, a pharmacy shall ensure that the patient receives written notice: (A) Of his or her right to request consultation; and (B) A telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record." Thus, when a new prescription is either mailed or delivered, the responsibility is shifted to the patient to request a consult.

31. [b] is the correct answer.

Section 1717[d] of Title 16, Calif. Code of Regulations allows a California pharmacy to fill and refill prescriptions for nonscheduled controlled substance drugs from prescribers who are licensed in other states. The regulation allows such prescriber prescriptions to be treated as though they were written by a California physician. Assuming that out-of-state licensed physicians also have DEA federal registration, then such physicians may also write prescriptions (must be on security prescription forms from an approved printer in California) for Schedule III, IV or V controlled substances to be filled and refilled in this state. Schedule II prescriptions from out-of-state prescribers may be honored in California if the Schedule II prescription is written on a California security form issued to the prescriber from another state. (See Calif. Health & Safety Code, Sec. 11164.1). Further, "a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed."



32. [a] is the best answer.

Section 4059[a] of the Calif. Bus. & Prof. Codes states that, "No person shall furnish any dangerous drug, except upon the prescription of a physician and surgeon, dentist, podiatrist, or veterinarian." If the pharmacy had a prescription of this medication on record, then a reasonable emergency supply of the drug could be provided. Since there is no record, it would be illegal for the pharmacist to give this patient any of the *Digoxin*. There is perhaps one way around giving the patient an emergency supply in this case, but it would take an extension of the facts. If the pharmacist were to call the patient's pharmacy in Texas and request a copy. Even though there might not be any remaining refills, the California pharmacist has essentially created a prescription record for the patient and would most likely be able to extend an emergency supply based upon this action. However, the facts in the question don't provide us with a statement that the pharmacist created a prescription copy from the Texas pharmacy after calling them. Therefore, you must assume there is no prescription record created.

There is another issue that surfaces in this question, and that is the placing of a small supply of the *Digoxin* in the patient's original container from the Texas pharmacy. This too is a violation of the law according to Section 1717[a] of Title 16, Calif. Code of Regulations which requires that each time a medication is dispensed on a prescription that a new container be used.

As to whether or not what was done was in the patients best interest is probably not a difficult issue to assess. The patient had been on the medication for the last past 10 years, and it is without question a drug she needed. Therefore, based upon this need, it would be in the patient's best interest to give her the drug.

33. [e] is the correct answer.

A pharmacist may not supervise any more than two pharmacist interns at any one time (see Calif. Business &

Professions Code, Section 4114[b]). Therefore, two pharmacists may have up to four pharmacist interns to supervise. At the same time, one pharmacist may only have one pharmacy technician, and the second pharmacist on duty may have up to two pharmacy technicians (see Calif. Business & Professions Code, Section 4115[f][1]). Thus, two pharmacists may have up to three pharmacy technicians working at the same time the four pharmacist interns are on duty.

34. **[b]** is the correct answer.

Section 11056[f] of the Calif. Health & Safety Codes classifies *Chorionic Gonadotropin (HCG)* as a Schedule III drug.

35. **[e]** is the correct answer.

Section 1707.2 of Title 16, Calif. Code of Regulations states both what must, as well as what may be consulted on during a patient consultation on a new prescription drug. Section 1707.2[c] states the mandatory consultation requirements, "When oral consultation is provided, it shall include at least the following:

- 1) Directions for use and storage and the importance of compliance with directions; and
- 2) Precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

- 1) The name and description of the medication;
- 2) The route of administration, dosage form, dosage, and duration of drug therapy;
- 3) Any special directions for use and storage;
- 4) Precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
- 5) Prescription refill information;

- 6) Therapeutic contraindications, avoidance of common severe side or adverse effects...;
- 7) Action to be taken in the event of a missed dose.

36. [b] is the correct answer.

Section 4312[b] of the Calif. Bus. & Prof. Codes requires that after a pharmacy license has been voided or where a pharmacy owner notifies the Board of the intent to remain closed, notification of such must be made to the Board within 10 days and all drugs must be arranged to be transferred to another licensee (pharmacy or wholesaler) and the Board so informed of the transfer in writing.

37. [a] is the correct answer.

According to Section 1718.1 of Title 16, Calif. Code of Regulations, "All prescription drugs not bearing a manufacturer's expiration date are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed.." (Also, see Title 21, Code of Federal Regulations, Section 1304.)

38. [d] is the correct answer.

According to a State Attorney General's opinion, a legitimate faxed prescription from a licensed prescriber's office to a pharmacy can serve as the original prescription record and may be used as the filed record. This includes all prescriptions for nonscheduled as well as for Schedule III, IV, and V controlled substances. (See also Calif. Bus. & Prof. Code, Sec. 4070[b].) The pharmacist is responsible for ensuring that the transmitted document came directly from the prescriber or an authorized employee of the prescriber and that all information required by law is present on the prescription, including the individual who is faxing it.

What if the prescriber faxed a prescription for a Schedule III, IV, or V controlled substance on either a regular or a special security prescription form? You cannot accept either of these faxed forms as your prescription of record since the law requires that a prescription for a

Schedule III, IV, or V controlled substance must be on a non-faxed special security prescription form as of January 1, 2005. In the alternative, a faxed prescription, whether it is on a security or regular prescription blank can be treated like a telephonic order after verification of authenticity and the name or initial of the party transmitting the prescription. If treated like a telephonic order, the pharmacist would have to reduce it to writing on his or her regular prescription blanks. By this means Schedule III, IV, V faxed prescriptions can be honored.

39. [b] is the correct answer.

Section 4052.5[a], Bus. & Prof. Code, reads in pertinent part, "...a pharmacist filling a prescription order for a drug product may select a different form of medication with the same active chemical ingredients of equivalent strength and duration therapy as the prescribed drug (this may be done without contacting the prescriber for his or her approval) when the change will improve the ability of the patient to comply with the prescribed drug therapy." The intent of the law was to benefit the patient in providing him or her with a dosage form that would allow for ease of use and proper compliance such as providing a young child with an equivalent dose in oral liquid form instead of a capsule that might be difficult for the child to consume. The law did not intend to benefit the pharmacist or pharmacy because they did not have a specific form of the drug in stock. As a practical matter, a dermatologist would more than likely argue that there is a difference in absorption rates and possible effect in regards to the use of a cream versus an ointment containing the same active ingredient.

40. [d] is the best answer.

According to Section 4067[a], Bus. & Prof. Code, "No person shall dispense or furnish dangerous drugs on the Internet to any person in this state without a prescription issued pursuant to a good faith prior examination or appropriate prior examination..." A prescription sent over

the Internet shall also indicate the name of the sender (Calif. Bus. & Prof. Code, Sec. 4071).

41. [a] is the correct answer:

Effective July 1, 2002 mercury fever thermo-meters may only be furnished pursuant to a prescription (Calif. Public Resources Code, Secs. 15025 & 15026).

42. [b] is the correct answer.

Section 1305.09 of Title 21, Code of Federal Regulations states that after DEA Form 222's Copy 1 and 2 are sent to the supplier intact, the supplier fills the order and retains Copy 1 and forwards Copy 2 to a Regional DEA office. The pharmacy or purchaser retains Copy 3 and when the supplies come to the pharmacy, the purchaser shall record on Copy 3 the number of commercial or bulk containers furnished on each item ordered and the dates on which such containers are received by the purchaser.

According to Section 1305.13 of the same code, the Copy 3 order form is required to be kept available for inspection for a period of 2 years. California requires the record be kept for 3 years.

43. [a] is the correct answer.

Section 1793.3 of Title 16, Calif. Code of Regulations states in pertinent part, "At the direction of the registered pharmacist, a non-licensed person (such as a pharmacy clerk) may... request and receive refill authorization."

44. [b] is the correct answer.

A non-pharmacist may own a pharmacy since no restrictions exist in either Section 4110 or Section 4111 to disallow such ownership rights. However, only a registered pharmacist may legally be involved in the filling of prescriptions and have possession of the key to the pharmacy.



45. **[b]** is the correct answer.

The answer to this question several years ago was that a patient who did not want to have his or her prescription information available in a common electronic network filing system, such as is available in chain pharmacy operations, would be required to sign a statement disallowing such transfer of information to occur, and the answer would have been “b.” This was stated in Title 16, Calif. Code of Regs., Sec. 1717.2[b]. However, since March 25, 2007 this signing requirement to prevent patient information from being placed in a common electronic filing system is no longer stated as a result of the repeal of Sec. 1717.2. Section 1717.1[e] of the same code however states, “Pharmacies maintaining a common electronic file shall develop and implement written policies and procedures designed to prevent the unauthorized disclosure of confidential medical information.” Based on this section of the regulations, patients still have a right to have their information withheld from entry into a common electronic network filing system.

46. **[c]** is the correct answer.

Section 1717[e] of Title 16, Calif. Code of Regulations states the following for scheduled controlled substance prescriptions, “A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes.” However, Title 21, Code of Federal Regulations, Section 1306.25[a] only allows for a one time transfer of refills for a controlled substance prescription. The sending pharmacy must void all of the remaining refills and must indicate in writing (usually on the back of the prescription) that there is a record of the prescription as having been transferred, and the date of the transfer. The receiving pharmacy upon creating the transferred prescription, shall identify it as a transferred prescription, and record the date of transfer and the original prescription number. Information maintained by each pharmacy shall include:

- a. Identification of pharmacist(s) transferring information.
- b. Name and identification code or address of the pharmacy from which the prescription was received or to which it was transferred.
- c. Original date and last dispensing date.
- d. Number of refills and date originally authorized.
- e. Number of refills remaining but not dispensed.
- f. Number of refills transferred.

While the transfer of a Schedule III, IV or V controlled substance prescription with refills to another pharmacy is only allowed one time, the transfer of nonscheduled drug prescription between pharmacies is allowed multiple times - as many times as there are remaining refills. Every time the prescription is transferred, as in the case of a scheduled drug prescription transfers, the sending pharmacy must void the prescription of any future refills.

47. **[b]** is the correct answer.

This is a rather tricky question. The answer is to be based upon Calif. Health & Safety Code, Sec. 11200[b] that reads, "No prescription for a Schedule III... substance may be refilled more than 5 times and in an amount, for all refills of that prescription taken together, exceeding a 120 day supply." Even though a 120 days would be exceeded by giving the 5<sup>th</sup> refill, the 120 day supply of the drug would not be exceeded. If the patient were to take the drug, using it continuously as prescribed, through the 5 refills on the basis of one tablet every 4 hours, that would under reasonable circumstances translate to 4 to 6 tablets daily. Thus, a 30 tablet supply for each time the prescription is refilled would total between a 5 to 7 day supply. Five refills would account for approximately a 25 to 35 day supply and not a 120 day supply. Remember, it is the number of days of supply that must be taken into account and not the days the patient gets her refills within the 6 month authorized period.

What is also a bit tricky about this question is if I had placed the monthly interval at the 20<sup>th</sup> of each of the months instead of the 10<sup>th</sup>, the 5<sup>th</sup> refill could not be refilled since it would be beyond the 6 month period from the date the prescription was originally written (Jan. 13, 20xy). Therefore, always be careful in reading questions where dates are given or referred to.

48. [b] is the correct answer.

Section 4301[n] of the Calif. Bus. & Prof. Codes notes that any disciplinary action taken by another state regarding a pharmacist's license shall constitute grounds for disciplinary action against a license in this State.

49. [b] is the correct answer.

Section `1707.1[a] of Title 16, Calif. Code of Regulations states, "A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy." Therefore, the pharmacist is given discretion as to his or her belief whether or not a patient will return to have a prescription filled or refilled. For the patient who comes into a particular pharmacy for the first time with a prescription, and that prescription has refills, it would seem more than likely that the patient would return to the same pharmacy for the refills - thus, requiring that the pharmacist prepare a patient medication profile on that patient. If there were no refills coupled with no evidence the patient would return, then no medication profile need be kept on that patient.

50. [a] is the correct answer.

Special security prescriptions for the prescribing of Schedule II, III, IV, and V controlled substances may be formatted in such a way to allow for several controlled substance drugs to be placed on one prescription. The key is

that the security prescription must be constructed in such a way as to allow for several Scheduled drug entries, and more importantly there must be an imprinted statement usually at the bottom of the security prescription that states, *“This prescription is void if the number of drugs prescribed is not noted.”* The number of scheduled drugs prescribed on the prescription would generally be noted after this statement. See Calif. Health & Safety Code, Section 11162.1[a][8].

51. **[a]** is the best answer.

According to Section 11200[b] of the Calif. Health & Safety Codes, “No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply.” Since the first refill is for a 100-day supply, by filling the second refill you will exceed the 120-day allowance.

52. **[d]** is the best answer.

Section 1717.3[b] of Title 16, Calif. Code of Regulations states, “A person may dispense a dangerous drug, that is not a controlled substance, pursuant to a preprinted multiple check-off prescription blank and may dispense more than one dangerous drug, that is not a controlled substance, pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs he or she has prescribed.” The prescriber does not have to be called for verification as long as the pharmacist has good reason to believe that the prescription items checked-off are in fact what the prescriber ordered for the patient. Prior to September 1, 2001, “e” was the correct answer whereby this type of preprinted multi-drug prescription could only have one nonscheduled prescription drug checked-off in order to be valid.

53. **[b]** is the correct answer.

In April 2002 the U.S. Supreme Court in *Thompson v. Western States Medical Center* found the FDA Modernization Act of 1997 unconstitutional regarding the restriction on disallowing advertising by pharmacies engaged in compounding, that it compounded a particular drug, drug class, or drug type products. As a result, pharmacies that do specialized compounding, can now advertise that they compound specific drug products. Prior to this decision a pharmacy could only advertise that they did general compounding, but not compounding of specific products.

54. **[c]** is the most correct answer.

Section 1745 of Title 16, Calif. Code of Regulations allows for the partial filling of Schedule II controlled substances if the prescription is for an inpatient of a hospice who is a terminally ill patient. The prescription must be partially filled within 60 days from the day it is written and that no portion of the prescription is dispensed more than 60 days from the date of issuance of the prescription.

The following are reasons why the other responses are wrong:

- Section 4184 of the Calif. Bus. & Prof. Codes prohibits the dispensing of Schedule II controlled substances from a clinic.
- If the patient requested less than what was written for on the security prescription, this would require the approval of the prescriber according to Section 1716 of Title 16, Calif. Code of Regulations. If the patient wanted the remainder of what was left on the security prescription, Section 11200[c] of the Calif. Health & Safety Codes would prohibit this since the refilling of Schedule II drugs from the same prescription is forbidden unless the patient was terminally ill and confined to a skilled nursing facility.



- In regards to the storing of Schedule II, III, IV and V controlled substances in a pharmacy, Section 1301.75[b] of Title 21 Code of Federal Regulations states that “Schedule II, III, IV and V controlled substances in a pharmacy may be dispersed throughout the stock of nonscheduled controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.”
- As to the filing of filled Schedule II prescriptions, Section 1304.04[h][1] of Title 21, Code of Federal Regulations states, “Schedule II prescriptions shall be maintained in a separate prescription file...” Thus, Schedule II prescriptions cannot be filed with other Schedules or nonscheduled prescriptions.

55. [d] is the correct answer.

When a prescription for a schedule controlled substance that has the potential of causing central nervous system depressing effects such as *Valium*, both a label stating that the drug may cause drowsiness (Section 1744 of Title 16, Calif. Code of Regulations) and that the drug should not be transferred to another person other than the person it was prescribed for (21 USC 825[c]) is required by law each time the drug is dispensed.

There is no requirement, according to the law, that a patient medication guide from the manufacturer must be provided to the patient each time the drug is dispensed as of this date of this publication. Nor is there a requirement that a verbal consultation on the medication be provided by the pharmacist upon a refill of the drug (Section 1707.2 of Title 16, Calif. Code of Regulations).

56. [b] is the correct answer.

According to the Title 16, Calif. Code of Regulations, Section 1735.2[c], “Prescriber office use means for application or administration in the prescriber’s office, or for distribution of not more than a 72 hour supply to the prescriber’s patients...” Therefore, a 7 day supply would exceed the requirements under the law.

57. [C] is the correct answer.

Under the federal rules, specifically Title 21, Code of Federal Regulations, Section 1304, and also contained in Title 16, Calif. Code of Regulations, Section 1718 it states that the Controlled Substances Inventory taken every two years by a pharmacy must be kept as record for at least three years from the date of the taking of the inventory.

58. [b] is the correct answer:

There is no one time allowance in the filling of a Scheduled drug on a regular prescription blank. Any prescription that is written for a Scheduled controlled substance must be written on a special security prescription form – there are no exceptions. See Calif. Health & Safety Code, Section 11162.1 & 11164[a]. The only way around this is to instruct the prescriber he must order the special security forms, and in the meantime he or she can call in prescriptions for Schedule III, IV, or V controlled substances that can be reduced to writing on a regular prescription form in the pharmacy by the pharmacist in order not to compromise good patient pharmacy care.

59. [d] is the more correct answer:

According to Calif. Health and Safety Code, Section 11159.2, that took affect on January 1, 1999, a prescriber may write a prescription for a terminally ill patient using a regular prescription blank other than a special security prescription form. Now that all Schedule II prescriptions that are filled are to be electronically transferred to a central data collection agency on a weekly basis, the need to send a copy of this prescription to the State's Department of Justice at the end of each month is not required as was the case when the *Triplicate* prescription for Schedule II's was used in the past. The primary purpose of this law appears to encourage prescribers to write for more potent analgesic agents for terminally ill patients who may be suffering extensively without having the prescriber be intimidated or

restricted by being fearful of using a special security prescription form.

60. [d] is the correct answer:

A certified optometrist can now write for a variety of other drugs including: a variety of oral antibiotics, a 3-day supply of oral codeine or hydrocodone when mixed with a nonscheduled drug, topical anti-inflammatory agents including steroids, topical anti-glaucoma agents, and topical antivirals including oral acyclovir. Oral anti-glaucoma drugs have recently been added to the list for prescribing. Injections of antibiotics (I.M. or I.V.) are not a part of the certified optometrist's allowable prescription writing list. See Calif. Business and Professions Codes, Section 3401.

61. [d] is the correct answer:

The regional DEA offices do not require that the once every two year inventory of a pharmacy's scheduled controlled substances be sent to the DEA. The inventory must, however, be kept at the pharmacy for at least a three year period after it is performed. Title 21, Code of Federal Regulations (CFR), Section 1304.04 and 21 U.S. Codes 827[a][b] indicate this maintaining of the inventory record by the pharmacy.

62. [b] is the correct answer:

According to Title 16, Calif. Code of Regulations, Section 1775.4, "Any person or entity served with a citation may contest the citation by appealing to the Board in writing within 30 days (not 60 days) of the issuance of the citation."

63. [d] is the correct answer;

An *Order of Abatement* basically requires, in the case of a pharmacist and pharmacy, that certain corrections within the licensed pharmacy be made within a given time in order for the pharmacy to be compliance with the law. Title 16, Calif. Code of Regulations, Section 1775.3 describes the requirements under this law.

64. [c] is probably the better answer:

I doubt very much that you would get a question like this one on the Board examination; however, this is the type of issue that could come up within one's practice setting. A question such as this one is generally more difficult to answer because of the thought analysis that must be applied, and that the result is based more on ethics rather than law. One way to approach the law portion of the question is to ask whether or not the pharmacist had a duty to fill this prescription. Upon receiving the prescription, the pharmacist decided not to fill it, therefore he or she may not have assumed the duty associated with the processing of this prescription, and thus could make the recommendation he or she did. While what was done may not necessarily be a violation of the law, it may certainly raise some issues of concern on the part of the patient's physician. Perhaps a more appropriate way in dealing with this situation is to contact the prescriber and discuss with him or her what you would like to do and why. In regards to whether or not your action as a pharmacist is in the patient's best interest, aside from creating any distrust between the patient and the physician, your action would appear to be more in the best interest of the patient with an intent of saving the patient money, and ensuring that they take the medicine in the dosage recommended by their physician.

65. [e] is the correct answer:

According to the FDA Report: FDA's Decision regarding Plan B oral emergency contraceptive sales (made publicly available on Aug. 24., 2006) the purchaser of Plan B

OTC emergency contraceptives may purchase more than one package whether it is for immediate or future use.

Answer a) is incorrect. The purchaser of the emergency contraceptive must be 17 years of age or older. Answer b) is incorrect since the item is being sold OTC, there does not appear to be any requirement that the pharmacist be certified through a training program in order to transact the sale. However, since the sale of these items requires the Plan B emergency contraceptive to be secured in the pharmacy area, a pharmacist or pharmacist intern should probably be the only ones involved in the sale of this item. Both answers c) and d) are also incorrect since at this time only levonorgestrel is the approved ingredient for sale OTC and no administrative fee for the OTC sale can be charged.

66. [c] is the correct answer:

If replacement contact lenses are dispensed pursuant to a prescription by a pharmacist, an expiration date “of not more than one year from the date of the last prescribing examination” may be used on the dispensed prescription container. This rule is in accordance with the Calif. Business and Professions Codes, Section 4124[b][2].

67. [a] is the more correct answer:

Calif. Business and Professions Codes, Section 4063 states in pertinent part, “No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.” Until the pharmacist can clarify with the prescriber a specific number of refills (between one and five within a six month period), the prescription should not be refilled.



68. [b] is the better answer:

In this example the pharmacist is in violation of Title 16, Calif. Code of Regulations, Section 1716 which states in pertinent part, "Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber..." *Vasotec 5 mg* was given instead of *Vasotec 10 mg*. The mistake, once known, has to be dealt with. The behavior of the pharmacist in not contacting the patient in an attempt to correct the mistake, is a circumstance that is not only not in the patient's best interest, but it is inexcusable and perhaps dangerous in regards to the patient's health and welfare. Furthermore, California pharmacists are required to prepare medication error reports subject to the Quality Assurance requirements mandated in Title 16, Calif. Code of Regulations, Sec. 1711. These reports are to assist the pharmacy and employees in preventing future medication errors.

69. [a] is the correct answer:

If a prescription is written by a physician assistant, nurse practitioner, certified nurse midwife, or a pharmacist pursuant to a prescriber's authorized protocol, the name of the prescriber no longer is required on the prescription label if the name of the furnishing P.A., N.P., C.N.M. or pharmacist's name is on the prescription label. See Calif. Business & Safety Code, Section 4076[a][4].

70. [a] is probably the better answer:

According to Title 21, U.S. Codes, Section 503[c][1], "No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample." If the drug sample was provided by a licensed prescriber to a retail pharmacy, based upon certain criteria that must be met according to Section 503[d] of the U.S. Codes, then the pharmacy could dispense it pursuant to an order by the authorized prescriber. The prescription sample drug would have to be

provided to the patient at no cost. The fact that the patient is not able to get this needed prescription drug elsewhere tends to give greater weight to it being 'in the best interest of the patient' when dispensed to the patient even though the patient is charged the nominal fee.

71. [c] is the correct answer:

A pharmacist and pharmacist-intern (and not the pharmacy technician nor clerk) are the only pharmacy personnel that may validate the information on a prescription to ensure that it is correct once the new prescription has been called in or physically brought into the pharmacy. This requirement is noted in Title 16, Calif. Code of Regulations, Sec. 1793.1[a][c].

72. [d] is the correct answer:

The operative law to answer this question is found under the Calif. Business and Professions Codes, Section 4073[a][e]. Section 4073[a] states that, "A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form..." Section 4073[e] requires that, "When a substitution is made..., the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label..." Concerning this latter point, the patient must agree to the drug substitution once being told of the cost saving advantage.

73. [c] is the correct answer:

According to the Calif. Business and Professions Codes, Section 4100 a licensed pharmacist must notify the Board of Pharmacy within 30 days of his or her change of name or address.

74. **[b]** is the correct answer:

Prior to 2004, veterinary drugs that were possibly considered dangerous or were comparable to human prescription drugs for the most part could be sold over-the-counter. That has now been changed whereby those veterinary drugs that are considered as dangerous, and designated as “dangerous drugs” will bear the following on the package labeling, “*Caution, federal law restricts this drug to use by or on the order of a licensed veterinarian,*” or words of similar import according to the California Business & Professions Code, Section 4042[a][b].

75. **[b]** is the correct answer:

Presently, there is no provision in the law requiring a pharmacy technician to pass a Board examination to receive certification. However, there has been discussion by the Board to consider in the near future the possible requirement that new pharmacy technicians pass a Board examination for certification.

76. **[b]** is the correct answer:

While a multispecialty clinic can dispense whatever amount is called for on a prescription, a surgical clinic is limited to what it can dispense pursuant to a prescription order. Under the Calif. Business and Professions Codes, Section 4190[b], as it pertains to surgical clinics, it states, “Drugs shall not be dispensed in an amount greater than that required to meet the patient’s needs for 72 hours.” This restriction does not appear to apply to multispecialty clinics.

77. **[c]** is the better answer:

The right to have information pertaining to one’s medical condition and drug therapy is generally protected under a U.S. Constitutional right to privacy. While there is no general federal rule that establishes a pharmacist-patient confidentiality privilege, there is a regulation providing administrative protection against a pharmacist giving out information about a patient’s medications or medical condition without the patient’s consent. Title 16, Calif. Code

of Regulations, Section 1764 which reads, "No pharmacist shall discuss or reveal the contents of any prescription, the nature... of illness suffered by any patient or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative, the prescriber or other licensed practitioner then caring for the patient, another licensed pharmacist serving the patient, or a person duly authorized by law to receive such information." Even though the patient in this case is a 16 year old child, she is awarded the same protection of privacy even if a parent would like access to the prescription information. Accordingly, since the pharmacist followed the regulatory requirement, he or she will have been acting in the best interest of the patient. This right of privacy is further enhanced by the protections afforded to individual patients under the HIPAA (Health Insurance Portability and Accountability Act of 1997).

78. [d] is the correct answer:

Calif. Business and Professions Codes, Section 4402[a] states, "Any pharmacist license that is not renewed within 3 years following its expiration may not be renewed..., and shall be canceled... at the end of the 3 year period."

79. [a] is the correct answer:

According to Title 16, Calif. Code of Regulations, Section 1717.4[c] the prescriber's address, license classification and federal registry number may be omitted if they are on file and readily retrievable in the receiving pharmacy.

80. [c] is the best answer.

Section 4064[a] of the Calif. Bus. & Prof. Codes states, "A prescription for a dangerous drug may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well being." The pharmacist

could certainly give this patient a small supply of the drug (72 hours worth), but this may be more dangerous than giving the patient a full month's supply. Note that the regulation allows for a refill for the amount that the patient had previously gotten. Therefore, there does not appear to be any issue with giving at least a one-month supply until the physician can be reached. If this were a Scheduled III, IV, or V controlled substance prescription, the pharmacist would only be able to provide a portion of the drug on refill until the prescriber could be reached to approve the quantity that was originally written for.

81. [b] is the more correct answer:

Calif. Health and Safety Codes, Sec. 11201 allows a pharmacist to refill a Schedule III controlled substance for a *reasonable* amount "without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if in the pharmacist's professional judgment, failure to refill the prescription might present an immediate hazard to the patient's health and welfare or might result in intense suffering." While a 72 hour supply might be the amount commonly supplied in an emergency circumstance in practice, the law only addresses the provision of a *reasonable* supply making [b] the more correct answer.

82. [d] is the correct answer:

At present there is no law requiring that the pharmacy must post the prices of all or specific drugs. All that is required (Title 16, Calif. Code of Regulations, Sec. 1707.2[f]) is that there be a posted notice statement alerting that "this pharmacy shall provide the current retail price of any prescription without obligation..."



83. [b] is the correct answer:

Title 16, Calif. Code of Regulations, Sec. 1705 requires that any pharmacy who is placed under a receivership shall notify the Board of Pharmacy immediately in writing.

84. [b] is the correct answer.

While Calif. Health & Safety Code, Sec. 11100[g][3] restricts the sale of ephedrine, psuedoephedrine, or norpseudoephedrine to 9 grams or 3 packages as a single transaction, the federal standard according to the Office of Diversion Control (noted 10/4/2006) limits the daily sale per customer to 3.6 grams and no more than 9 grams per month. This latter amount (up to 3.6 grams), based upon the federal law, is to be followed for each individual sale of the product.

85. [e] is the more correct answer:

Title 16, Calif. Code of Regulations, Sec. 1715[a][b] places the responsibility of completing the Self-Assessment Form with the pharmacist-in-charge. The form is to be filled out before July 1<sup>st</sup> of every odd-numbered year and is to be maintained in the pharmacy (not sent to the Board or other agency) for three years. If a state Board inspector comes to inspect the pharmacy, this filled-out Self-Assessment Form will be one of the items most likely to be reviewed by the inspector.

86. [d] is the more correct answer:

While the law (Calif. Bus. & Prof. Codes, Sec. 4122) allows for a request of 5 or more prescriptions prescription price inquires to be reasonably charged for; however, there is nothing in the law that suggests that the pharmacist add the price quote charge to the cost of the filling the prescriptions. Thus, answer [d] becomes the least correct, since all the other choices are supported by the law.

87. [e] is the correct answer:

While California's Business and Professions Code, Section 4052[a][9] allows a pharmacist to administer immunizations under the supervision of a prescriber, the Board of Pharmacy provided more substance to the actual implementation of such programs that are expressed in choices [b], [c] and [d]. The National Vaccine Injury Compensation Program only protects the pharmacist against adverse reactions caused by the administration of a vaccine, but does not cover acts of negligence caused by the pharmacist during the vaccine administration (example: using a dirty needle that infects the patient or injecting the patient in the wrong area causing nerve damage.)

88. [b] is the correct answer:

Any pharmacy that dispenses replacement contact lenses shall register with the Medical Board of California. (Calif. Bus. And Prof. Codes, Sec. 4124[g]).

89. [a] is the correct answer:

There is no mention in Title 16, Calif. Code of Regulations, Section 1711 that the pharmacy must forward all or any medication error reports to the California State Board of Pharmacy. All the other multiple choice answers are required by 1711.

90. [e] is the more correct answer:

Working for two different employers for 40 hours or less each per week causing the sum to exceed 40 hours a week, is still an exception to the non-exempt pharmacist status and this is an allowable arrangement even though it is not written into the code. The 40 hour work-week applies

only to the place of employment where the employee-pharmacist is hired full-time. If the pharmacist wishes to work full-time for one employer, and part-time for another employer, the full-time employer is not penalized with overtime pay for the additional part-time work undertaken by an employee-pharmacist at another pharmacy. (See Calif. Labor Codes, Sections 510 to 558.)

91. [e] is the correct answer.

In 2004 the FDA banned all sales of ephedrine or ephedrine-like herbal agents over-the-counter.

92. [d] is the most correct answer:

When a nonscheduled prescription with refills is transferred between pharmacies according to Title 16, Calif. Code of Regulations, Sec. 1717[e] both the sending and the receiving pharmacies must record on the back of the prescription the name of the pharmacist involved in the transfer. Thus, the name of the sending pharmacist must appear on the receiving pharmacist's prescription, and the name of the receiving pharmacist must appear on the sending pharmacist's prescription. Remember, for nonscheduled prescriptions there may be as many transfers between pharmacies as there are refills, but each time the sending pharmacy transfers the remaining refills, the sending pharmacy prescription becomes void regarding remaining refills.

93. [b] is the correct answer.

According to Title 16, Calif. Code of Regs., Sec. 1707.5 that states in pertinent part regarding the printing on the patient's label, "...each item shall be printed in at least

10-point *sans serif* typeface or, if requested by the consumer, at least a 12-point typeface...” Additionally the code continues to describe that 50% of the labeling clustered in one area of the label shall contain the following information: 1) name of the patient, 2) name and strength of the drug, 3) the directions for use, and 4) the condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription. It is also suggested that the four items above be highlighted in bold type face or color, or be set on a color background that differentiates this information from the other information that will also be placed on the label.

94. [d] is the correct answer.

Title 16, Calif. Code of Regulations, Sec. 1744 requires auxiliary labeling for those drugs that could impair a person's ability to drive a motor vehicle when taken alone or in combination with alcohol. Also included are drugs that may have other harmful effects when taken in combination with alcohol. Thus, all agents that cause drowsiness, that impair vision, or have dangerous results when taken with alcohol must by law have an auxiliary label indicating the possible danger. Such drugs as Pepcid have not shown evidence of the type of adverse effects that would warrant the type of cautionary labeling that the other agents would require.

95. [C] is the correct answer:

According to Title 16, Calif. Code of Regulations, Section 1707.2[b][2][A][B] the only requirement in the delivery of a new prescription to a patient at their home or office is to ensure that the patient receives written notice of his or her right to request a consultation, and that a telephone number is available for the patient to call if he or she has a question about his or her new prescription medication.

96. [d] is the more correct answer:

According to new federal rules, the monthly sale of an ephedrine-like product (e.g. pseudoephedrine or ephedrine) are restricted to 9 grams per month per customer, and these products must be stored in a secure area such as behind the pharmacy counter.

97. [d] is the correct answer:

The United States Pharmacopeia standard is to be applied regarding the repackaging of drugs in unit doses by pharmacies. In 2000 the U.S.P. changed the requirement on expiration dating to be used on extemporaneous unit dose packages. The old U.S.P. rule was to use an expiration date that was either 1/4<sup>th</sup> the expiration date on the drug manufacturer's container, or 6 months, whichever was less. The present U.S.P./N.F. rule is to allow one year from the date of preparing the extemporaneous unit dose packets or less if the date on the drug manufacturer's package is less than one year (USP24/NF19; 1991:2589-90).

98. [d] is the correct answer.

A pharmacy that wishes to have a facility off-site to store its prescription records, must have a waiver (not a license) from the Board of Pharmacy. (Title 16, Calif. Code of Regulations, Sec. 1707[a])

99. [d] is the correct answer.

The Board of Pharmacy may issue a temporary permit for a period not to exceed 180 days, during a transfer of pharmacy ownership, in order that the pharmacy continue its pharmacy operations during the ownership transition period (Calif. Bus. & Prof. Code, Sec. 4110[b]).



100. **[C]** is the more correct answer:

Title 16, Calif. Code of Regulations, Sec. 1714.1[b][c][d][e][f] states in pertinent part, “during the pharmacist’s absence, no prescription medication may be provided to a patient unless the prescription medication is a refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.” It is also important to note that the activities of the pharmacist-intern become non-discriminatory during the pharmacist’s absence.

101. **[a]** is the correct answer:

Calif. Bus. and Prof. Codes, Sec. 4078[b] provides an exception to the so-called rule, “truth in labeling.” According to Section 4078[b] a prescription label may contain information about a prescription drug that is false: 1) if the labeling is a necessary part of a clinical or investigational study approved by the FDA, or 2) if, in the medical judgment of the prescriber, the labeling is appropriate for the proper treatment of the patient.

102. **[b]** is correct answer.

Title 16, Calif. Code of Regulations, Sec. 1711[d] requires that an investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days (48 hours during the workweek) from the date the medication error is discovered.

103. **[d]** is the more correct answer:

Title 22, Calif. Code of Regulations, Sections 7026.3 and 7026.5 require that a pharmacist at least serve in the capacity of a consultant to the 100 or less bed hospital. Neither a full-time nor a part-time pharmacist is required even though most hospitals of around 100 beds will more than likely have full-time or part-time pharmacists on their staff.

104. [b] is the correct answer:

Calif. Bus. and Prof. Codes, Sec. 4312[b] states in pertinent part, "In the event that the license of a pharmacy is voided or revoked, or the pharmacy notifies the Board of its intent to remain closed or discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances." Once the drugs have been transferred it is required that the licensee transferring the drugs immediately confirm in writing to the Board that the transfer has taken place.

105. [e] is the correct answer:

The Calif. Health and Safety Codes, Sec. 11256 states that, "within 24 hours after any purchaser in this state gives any order for a Schedule II controlled substance, or makes any contract or agreement for purchases from or sales by, an out-of-state wholesaler or manufacturer of any controlled substances for delivery in this state, the purchaser shall forward to the Attorney General registered mail a true and correct copy of the order, contract, or agreement."

106. [c] is the more correct answer:

As of January 1, 2002 every pharmacy in California will be responsible for documenting medication errors for the purposes of assessing those errors so that the pharmacy may take appropriate action to prevent a recurrence. Policy and procedures will outline the method of documentation and how it will be used to decrease the recurrence of such errors. Records of medication errors shall be maintained by the pharmacy for at least one year from the occurrence or discovery of the error. (Title 16, Calif. Code of Regs., Sec. 1711[c][e][f].)

107. [c] is the correct answer:

According to Title 16, Calif. Code of Regs, Sec. 1715[a][d] the self-assessment must be completed every 2 years, but must be retained by the pharmacy for 3 years.

108. [e] is the more correct answer:

If the pharmacist contacts the prescriber to correct the error on the security prescription, the prescription may be filled and dispensed as corrected. The prescriber does not have to write a new security prescription. However, the pharmacist is still responsible for documenting the changes made and note that it was authorized by the prescriber - it is not required that the prescription be sent back (mailed or emailed) to the prescriber for a second signature that would serve as an acknowledgement that the prescriber authorized the correction.

109. [a] is the correct answer.

The HIPAA rule requires that each patient be given notice of his or her privacy rights and how the patient's information is to be used; and that a good faith effort be made to acquire the patient's signature acknowledging his or her receipt of the HIPAA information. If the patient chooses not to sign the notice, the party providing the notice can so note that the patient declined signing, and indicate that the patient was made aware of the intent of the HIPAA rule. This need only be done one time for each patient, and the signed or unsigned (with the refusal to sign statement entered by the provider) must be kept as record for at least six years.

110. [a] is the correct response.

A certified nurse midwife (CNM) may only write for Schedule controlled substances pursuant to a prescriber's protocol if he or she has a valid DEA registration. See Calif. Business & Professions Code, Sections 2725.1 & 2746.51 and Calif. Health & Safety Code, Sections 11026 & 11150. All the other activities noted as answers may be performed by the CNM pursuant to a written prescriber directed protocol.

111. **[d]** is the correct answer.

All prescription orders initiated by a prescriber for Schedule II, III, IV, and V controlled substances must be written for on a special security prescription form. See Calif. Health & Safety Code, Sections, 11162.1[a] & 11164[a]

112. **[b]** is the more correct answer:

Under the FDA standards and the Code of Federal Regulations while there is no general statement regarding a pharmacy taking back a prescription drug that was dispensed to a patient with the intent to reuse the drug for another prescription from another patient, it is prohibited to use a drug dispensed to one patient that brings the drug back to the pharmacy to be dispensed to another patient based upon the rulings associated with drug adulteration. Once the pharmacy loses custody over the drug, as a matter of principle, it should not be used or dispensed to another for fear that the drug may have been adulterated. While the pharmacy may certainly take the drug back from the first patient and reimburse the patient for allegedly not using it, the pharmacy cannot turn-around and dispense that same drug to another patient since it will be considered adulterated.

113. **[b]** is the more correct answer:

California Senate Bill 188 (2000 Session and incorporated as law into the Calif. Bus. & Prof. Code, under Section 4056[a][f] ) was passed to allow hospitals of 100 beds or less to purchase drugs in order to be dispensed by physicians to: a) persons registered as inpatients of the hospital; b) emergency cases under treatment in the hospital, and c) outpatients of a rural hospital. Regarding item c) above, the outpatients of the hospital must be relatively isolated from outpatient prescription services, and reasonably unable to get the prescribed drugs in a timely and convenient manner. A general definition of a rural hospital is that other pharmacy services are not available within a 30 minute or 30 mile relationship to the rural hospital.

114. [a] is the correct answer.

Pharmacists (as well as physician assistants, nurse practitioners and certified nurse midwives) can now apply and receive a DEA registration allowing them to be the sole signers in the furnishing of Schedule III, IV, and V controlled substances pursuant to a prescriber directed protocol. (See Calif. Bus. & Prof. Code, Secs. 4040[a][1][F][2], 4052[b], and Calif. Health & Safety Code, Secs. 11150 & 11210.)

115. [d] is the more correct answer:

Both California Senate Bill 2046 and Calif. Health and Safety Codes, Sec. 1367.21 would allow an existing FDA approved drug to be used “off-label” for a life-threatening, chronic or disabling condition without FDA restrictions as long as there is sound and balanced, as well as reliable sources that support the use of the drug for the “off-label” purpose.

116. [e] is the most correct answer.

FDA regulations consider any drug package exposed to such elements as smoke, ashes, and/or moisture as being adulterated even though the drugs are well sealed and in boxes.

117. [a] is the correct answer.

An interpretation of Title 16, Calif. Code of Regs., Sec. 1711 would strongly suggest that a major unreasonable delay by a pharmacy and its pharmacists in the filling of a prescription that is required to be issued to a patient in an expedient manner would most probably be construed as a medication error, especially if the delay was not in the best interest of the patient’s well-being.



118. **[d]** is the correct answer.

According to Title 16, Calif. Code of Regulations, Sec. 1711[d] once the pharmacy discovers the medication error after the medication has been dispensed to the patient, it has two business days to initiate an investigation and prepare a report as part of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors.

119. **[b]** is the correct answer.

As a pharmacist you may compound for future use provided you maintain the following records (See Title 16, Calif. Code of Regulations, Section 1735.2):

- The date of the preparation.
- The manufacturer's lot numbers for each of the ingredients (active and inactive ingredients).
- The expiration date of the finished product, not to exceed 180 days if any of the ingredients has an earlier expiration date.
- The initials of the pharmacist performing the compounding
- A formula for the compounded product.
- Quality reviews required at each step in preparation of the compounded drug.
- Names of the manufacturers of the raw materials.
- The quantity in units of the finished product along with package size.

The only license required for compounding is if the compounding is for sterile products. Regular compounding of non-sterile products does not require a license from the Board of Pharmacy. A segment of the FDA Modernization Act of 1997 was struck down because it was found unconstitutional in preventing pharmacists from advertising specific products that they compound.

120. [d] is the most correct answer.

The form given to the patient is a “Notice” form and not a “Consent” form. According to the HIPAA regulations the patient does not have to sign the form even though it is suggested, they just have to be, through the provision of the Notice form, advised of where there medication information may routinely have to go – to others in the health care organizations, to billing, to third party payers, to the health care organizations committees that deal with patient assessment studies, etc.

121. [c] is the correct answer.

According to the California Bus. & Prof. Codes, Section 802 any settlement involving \$3,000 or more in a pharmacy-related law suit must be reported to the Board of Pharmacy within 30 days after the settlement arrangement is finalized.

122. [e] is the correct answer.

While the licensed optometrist who is certified to prescribe specific prescription drugs associated with the more common and superficial ophthalmological problems, the range of drugs allowed may not include injectable antibiotics according to the California Bus. & Prof. Codes, Section 3401[g]. The law has recently allowed optometrists who are certified to prescribe to write for oral drugs for open angle glaucoma. Further, it appears that the restriction of not allowing a optometrist to prescribe drugs for a child less than a year has been removed.

123. [e] is the correct answer.

According to California Bus. & Prof. Code, Section 733 a pharmacist who plans to refuse to fill a prescription for a given class or classes of drugs or devices is obligated to

notify his employer in writing upon being employed or at a time when such religious, moral or ethical concerns arise in order for the employer to establish a written policy setting forth the procedures that will ensure that the patient will receive the prescribed drug or device in a timely and reasonable manner. Such a policy would state other alternatives that can be taken to ensure that the patient is provided his or her drug or device without any unreasonable delay.

124. [C] is the more correct answer.

A pharmacist may be a pharmacist-in-charge of two pharmacies provided that the second pharmacy is not separated from the first pharmacy by a driving distance of more than 50 miles. (See Title 16, Calif. Code of Regulations, Section 1709.1[c].)

125. [C] is the correct answer.

The veterinary drug-food license must be renewed on a yearly basis. (See Calif. Bus. & Prof. Code, Section 4196[a].)

126. [e] is the more correct answer.

According to Title 16, Calif. Code of Regulations, Section 1793.3[a] there is no statement as to the limitation of the number of pharmacy clerks that may be employed at any given time. Further the regulation states that the clerks can type prescription labels, enter prescription information into a computer pharmacy record system, and request and receive refill authorizations. All of these activities, of course, must be under the supervision of the pharmacist on duty. The regulation does not state that there is a ratio of clerk to pharmacist requirement in the performance of these activities.

127. [a] is the correct answer.

It is stated in the California Health & Safety Code, Section 11164.5 that “with the approval of the California State Board of Pharmacy and the Department of Justice, a pharmacy or hospital may receive electronic data transmission of prescriptions or computer entry prescriptions... for controlled substances in Schedule II, III, IV, or V if authorized by federal law and in accordance with regulations promulgated by the DEA.” Electronic transmission of controlled substance prescriptions is presently allowed under the federal “e-prescribing” program.

128. [a] is the more correct answer.

It is clearly stated in the California Bus. & Prof. Codes, Section 4063 that “no prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.” However, since the prescription for the Scheduled III, IV or V controlled substance was written, and is clear as to the patient, the drug, the dose, the amount to be dispensed, the date, and clear and precise directions, the original prescription can be filled. The “*prn refill*” portion needs to be clarified with the prescriber and quantified as to the exact number of refills authorized.

129. [b] is the most correct answer.

The person in the pharmacy ordering Schedule II controlled substances from the wholesaler using the DEA Form 222 does not have to be a pharmacist. What is required is that the individual that is ordering the Schedule II drugs from a wholesaler is recognized by the DEA by registering with them. Others from the pharmacy staff may also order if they are authorized to do so under a “power of attorney” that has been previously submitted to the DEA. Regarding the other answers, only Schedule II’s are to be ordered using the DEA Form 222. The first copy of the DEA Form 222 is retained by the party filling the order for the Schedule II drugs such as the wholesaler with the second

copy being sent to the DEA offices. If physicians or other pharmacies wish to receive Schedule II controlled substances from your pharmacy, they must execute a DEA Form 222 for such ordering – the providing pharmacy must then submit the second copy of the DEA Form 222 to the DEA after filling the order, just as the providing wholesaler would have to do. (See 21 CFR, Sections 1305.05 & 1305.07.)

130. [d] is the correct answer.

A Schedule II controlled substance that is to be partially filled for a terminally ill patient, that prescription must be tendered and at least partially filled within 60 days following the date of issue. Furthermore, no portion of the prescription is to be dispensed more than 60 days from the date the prescription was issued. (See Title 16, California Code of Regulations, Section 1745[c][1][3].)

131. [b] is the correct answer.

As a matter of good pharmacy practice in order to ensure that a patient is properly administering a controlled substance to him or herself, the directions on the label should be clear as to frequency of usage of the drug. To simply place on the label “*Take prn or as directed*” provides no specificity as to the interval or period of time that the patient should be taking the controlled substance. Whereas, the direction “*Take one or two tablets every 4 hours as needed or directed for pain*” allows the pharmacist to know what the approximate usage of the drug is over time based upon the quantity dispensed. This is important for refill considerations and to ensure the patient is not overusing or abusing the controlled substance prescribed. “*Take prn or as directed*” appears to be acceptable as the direction for non-scheduled drug prescriptions presuming that the patient has full knowledge on how to take the drug correctly.



132. **[b]** is the correct answer.

If there is a mistake or error on the Schedule II prescription, it appears that the pharmacist need only contact the prescriber and make the necessary correction changes on the prescription noting that the prescriber has approved of such changes. Since the security prescription is used for all Scheduled controlled substances, handling the Schedule II errors or mistakes the same way that such errors or mistakes would be handled for Schedule III, IV, and V controlled substances provides for a uniform standard in correcting errors or lack of information for all prescription drugs whether non-scheduled or scheduled.

133. **[e]** is the correct answer.

While licensed naturopathic doctors (ND) can independently write for or furnish natural or synthetic hormones without being bound to a physician-directed protocol, if the natural or synthetic drug happens to be a Scheduled controlled substance such as testosterone (Schedule III) then the ND may only write or furnish the testosterone in accordance with a patient-specific protocol approved by a supervising physician. The ND would also require to have a DEA license if he or she were allowed to furnish the Scheduled drug pursuant to a physician-directed protocol. (See California Bus. & Prof. Codes, Section 3640.5[f].)

134. **[b]** is the correct answer.

According to California Bus. & Prof. Code, Section 4052[a][8][C] a pharmacy may only charge up to an administrative fee of \$10 for services rendered in addition to the retail cost of the emergency contraceptive drug dispensed as a prescription. If the emergency contraceptive drug is purchased by a consumer pursuant to Plan B as levonorgestrel sold over-the-counter, no administrative fee is to be charged.

135. [C] is the correct answer.

By statutory definition, a pharmacy is considered “closed if it is not engaged in ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.” (See California Bus. & Prof. Code, Section 4312[e].)

136. [d] is the correct answer.

The drug *Pregabalin* (*Lyrica*®) has federally been classified as a Schedule V controlled substance. So far it is the only drug classified as a drug used in the management of peripheral neuropathy and post-herpetic neuralgia that has been placed in the Scheduled drug category.

137. [C] is the correct answer.

The copy of the prescription that is sent by one pharmacy to another pharmacy is to be treated like a telephonic order by both pharmacies. As a result and according to California Code of Regulations, Section 1717[e] “...The receiving pharmacist shall create a written prescription, identifying it as a transferred prescription...” Regarding the faxed prescription copy by the sending pharmacy, that document can be attached as reference to the written prescription prepared by the receiving pharmacy.

138. [e] is the correct answer.

A federal controlled substance inventory form listing all of the prescription controlled substances must be filled out once every two years, and must be maintained as a record in the pharmacy for 3 years. (See Title 16, California Code of Regulations, Section 1718 & Title 21 CFR 1304.) Recently, the law was changed for clinic’s to retain their prescription records for 3 years instead of 7 years. See CA Bus. & Prof. Codes, Sec. 4180[a][2].

139. [d] is the correct answer.

Drugs that cause a central nervous system suppressing effect, blur the vision, or cause a severe interaction with alcohol require by law auxiliary labels that warn the patient of these problems. (See Title 16, California Code of Regulations, Section 1744.) Also, when a prescription for a Scheduled controlled substance is dispensed the law requires that an auxiliary label accompany the prescription that cautions the patient about transferring his or her controlled substance to another party unauthorized to receive the drug. (See 21 U.S.C. 825[c] and 21 CFR, Section 290.5.) Generally what is not required by law, but is a requirement of the manufacturer of a given product are such warnings and auxiliary labeling that instructs the patient to shake the product well before using, or to refrigerate the product.

140. [C] is the more correct answer.

A pharmacist has the authority to generically substitute a prescription drug for a patient without contacting the prescriber for permission to make the change provided that there is no indication by the prescriber that the drug cannot be substituted, the substitution must have at least the oral approval of the patient receiving the drug, and there is an indication to the patient that there will be a cost savings in receiving the generic substitution. (Calif. Bus. & Prof. Code, Sec. 4073)

141. [d] is the best answer.

The California codes do not appear to address this issue. As noted in the text some states allow the refilling of a deceased prescriber's prescription even when the pharmacist knows of the prescriber's status (e.g. North Carolina), while other states disallow the prescription refilling with the pharmacist's knowledge that the prescriber is deceased (e.g. Pennsylvania). Usually when there is no state law on point, the pharmacist could interject a reasonableness standard to

determine what would be in the best interest of the patient. As stated in Chapter 3 to support answer “d,” is to allow the pharmacist to assess the patient’s medical condition, and if it appears that the patient might be harmed or suffer as a result of not being continued on either a full or partial refill amount of the prescription medication, then the pharmacist may act accordingly in providing a partial or full refill. The pharmacist would also need to remind the patient that they need to be followed-up by a new prescriber who would be required to approve the patient’s continuance on the medications they are taking.

142. [e] is the correct answer.

Title 16, Calif. Code of Regs., Sec. 1709.1[d] states that “no pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the exemptee-in-charge for a wholesaler or a veterinary food-animal retailer.” In regards to the other possibilities, a) is incorrect since the driving distance between the two pharmacies cannot be more than 50 miles (Sec. 1709.1[c]). b) is incorrect since “a pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility would interfere with the effective performance of the pharmacist’s responsibilities under the pharmacy-based law (Sec. 1709.1[f].” c) is incorrect since a pharmacist may serve as a pharmacist-in-charge for two pharmacies and no more (Sec. 1709.1[c]). And d) is incorrect for the reason stated directly above (Sec. 1709.1).

143. [C] is the correct answer.

“Only general acute care hospitals that have an ongoing clinical program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock, and unit dose distribution systems for in patients whose orders have

previously been reviewed and approved by a pharmacist” according to Title 16, Calif. Code of Regs., Sec. 1793.8[a]. The pharmacy technician performing the checking must have specialized training and work in accordance with policy and procedures. Community pharmacies are not recognized under this regulation, nor is there the issuance of a special license by the Board for pharmacy technicians to be able to check the filling of inpatient medication orders by other pharmacy technicians.

144. **[b]** is the correct answer.

Under Plan B Emergency Oral Contraception, as stated in the U.S. FDA Report, “FDA’s Decision regarding Plan B (Aug. 14, 2006), the Plan B Emergency Oral Contraceptive may only be sold in pharmacies. Presently, only one drug ingredient exists under Plan B and that is two tablets of levonorgestrel 0.75 mg each. The purchaser must be at least 17 years of age. Because the drug is sold over-the-counter, no administrative fee (e.g. \$10.00) may be added to the sale. And, either the person taking the drug or an agent for the recipient may purchase the 2-tablet package. Further, the purchaser may buy more than one package at the time of sale.

145. **[a]** is the correct answer.

Calif. Bus. & Prof. Code, Sec. 4104 requires that if a board licensed employee admits to you as the supervising pharmacist or pharmacist-in-charge that he or she has been using drugs illegally, it must be reported to the Board of Pharmacy within 14 days once this fact is known. It is further customary that this employee be suspended from work pending an investigation or terminated from employment. Non-licensed parties such as clerks who admit to the illegal use of a drug taken from the pharmacy’s stock, do not have to be reported to the Board; however, the incident must be reported within 30 days to the Board because of the missing or stolen drugs.



146. **[d]** is the correct answer.

Even though gabapentin (Neurontin) is in the same chemical class as pregabalin (Lyrica), it is not designated as a Schedule V controlled substance.

147. **[e]** is the correct answer.

The ADDS device, according to Title 16, Calif. Code of Regs., Sec. 1713[d][6] may be located adjacent and outside of the pharmacy filling area; thus, being placed in a location allowing it to be used before the pharmacy is open, or after it closes.

148. **[b]** is the correct answer.

According to the federal Combat Methamphetamine Epidemic Act (CMEA) of 2005, ephedrine-like products, especially pseudoephedrine, may only be sold by a certified business such as a pharmacy in limited amounts of no more than 3.6 grams per day, or 9 grams total per month to a given purchaser. The older law, no longer in effect, allowed for 3 packages or up to 9 grams of pseudoephedrine for each purchase transaction. Further these ephedrine-like products must be kept in locked cases or behind the pharmacy counter, and not to be made easily accessible to the customers. Upon each purchase of these products, the sale must be recorded in a logbook containing the name, strength and quantity of the product sold; customer information that will include the customer's name, address, date, and time of sale; and the customer's signature. The only exception to the law is the allowance of single purchases of one 60 mg. pseudoephedrine unit dose package or a unit dose package containing 2-30mg. pseudoephedrine tablets – under this circumstance, no log entry by the customer or signature need occur.

149. **[C]** is the correct answer.

As a general rule, a pharmacist may not fill a prescription from another country. However, there are laws, both state and federal, that allows for the filling of prescriptions from the District of Columbia and the U.S. territories which include Puerto Rico, the Virgin Islands, Guam, and American Samoa. These exceptions are noted in the following codes:

- *Calif. Bus. & Prof. Code, Sect. 21: "State" means the State of California, unless applied to the different parts of the U.S. In the latter case, it includes the District of Columbia and the territories.*
- *4 USC, Sec. 110(d): The term "State" includes any Territory or possession of the United States. (Major U.S. recognized territories are Guam and the Virgin Islands are organized territories, but they are neither incorporated nor considered commonwealths. On the other hand, American Samoa is formally considered an unorganized territory, though it is self-governing under a 1967 constitution.)"*
- *Calif. Bus. & Prof. Code 4005(d) – allows the Board to adopt regulations that allow pharmacies to fill legitimate prescriptions written by prescribers of other states. And Title 16, Calif. Code of Regs., Sec. 1717(d) allows for the filling of out-of-state prescriptions.*

150. **[b]** is the correct answer.

Calif. Bus. & Prof. Code, Sec. 4059.5(a) states that "...prescription drugs may only be ordered by an entity licensed by the Board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative may sign for and receive the delivery." Based upon above can a pharmacy clerk be a designated representative? According to Calif. Bus. & Prof. Code, Sec. 4022.5(a) - "Designated representative" means an individual to whom a license has

been granted pursuant to Section 4053 (talks mainly about issuing a license to a representative-in-charge, or representative that operates a drug/medical device wholesale business or a veterinary food-animal drug business).

151. [C] is the correct answer.

The rendering of an opinion by the State's Attorney General's Office is not law, but is simply an opinion to help clarify an issue and allow for a standard that will be followed by all pharmacy practitioners. That opinion, for the most part, will establish a "standard of practice" that should be followed, and often has much of the same impact as a state statute or regulation.

152. [b] is the correct answer.

"All prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing." This is in accordance with Title 16, Calif. Code of Regs., Sec. 1707[f].

153. [a] is the more preferred answer.

While there is no established law in California on filling or not filling a prescription for a patient whose physician has died, because of the concern of doing what is in the best interest of the patient even though you know the physician has died, the pharmacist would, based upon a reasonableness standard, provide a partial or total refill of the prescription based upon the medical condition of the patient in considering the possible harm to the patient if they did not receive the medication, and the patient's need to not have an interruption in their therapy. You would also advise the patient that they need to be followed up by a new physician, and that you as the pharmacist would be happy to provide that new prescriber with the patient's past medication history.

154. [d] is the correct answer.

Warnings such as “refrigerate,” or “shake well” are manufacturer’s requirements and are generally not statutory or regulatory requirements, other than what the FDA may require of the manufacturer to ensure the drug is either stored or used properly. However, warnings such as “may cause drowsiness,” or “do not use with alcohol,” or “may cause blurring of the vision” are noted in the California regulations and require the pharmacy by law to have an auxiliary label placed on the prescription vial advising the patient to take necessary precautions. See Title 16, Calif. Code of Regulations, Sec. 1744. 21 U.S. Code, Sec. 825[c] and Title 21 Code of Federal Regs., Sec. 290.5 requires a pharmacy auxiliary label specifically prohibiting the patient to share their prescribed controlled substance drug with another person.

155. [d] is the correct answer.

Title 16, Calif. Code of Regs., Sec. 1711[f] states that the record of the quality assurance review (the “medication error report”) shall be kept at the pharmacy for at least one year from the date the record was created. There is no statement in the regulation that the document must automatically be sent to the Board of Pharmacy.

156. [e] is the correct answer.

A hypodermic log book used for the OTC purchase of hypodermic needles and syringes is no longer required since for the dispensing of prescription items that require a syringe or needle for human use will now require a prescription with some exceptions. If a patient who is on insulin, as an example, should not have a prescription for the needed syringes and needles, Calif. Bus. & Prof. Code, Sec. 4145.5[a] states that the pharmacy may furnish the necessary syringes and needles if the person is known to the pharmacist and he or she has previously been provided a

prescription or other proof of a legitimate medical need requiring the hypodermic needles and syringes to administer the medicine or treatment. The pharmacist can still call the prescriber to get approval, or have the patient bring in a prescription for the needles and syringes the next time they are to receive the injectable medication.

157. [b] is the correct answer.

Title 22 Calif. Code of Regs., Sec. 70163[q] requires that refrigerator temperatures for drugs be between 2.2°C (36°F) and 7.7°C (46°F). Room temperature requirements for the storage of drugs is to be between 15°C (59°F) and 30°C (86°F).

158. [b] is the correct answer.

Calif. Bus. & Prof. Code, Sec. 4114[b] states, "A pharmacist may not supervise more than two intern pharmacists at any one time."

159. [c] is the most correct answer.

Calif. Bus. & Prof. Code, Sec. 3041[c][14] states in pertinent part that a registered optometrist with a DEA license may prescribe codeine or hydrocodone mixed with a non-Schedule drug compound and shall be limited to writing for a three day patient supply with referral to an ophthalmologist if the pain persists.

160. [C] is the correct answer.

Calif. Bus. & Prof. Code, Sec. 4104[c] requires that the pharmacy shall report to the Board of Pharmacy within 14 days with specific information provided, on any personnel licensed by the Board who admits or is found to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice pharmacy.



161. **[C]** is the correct answer.

According to the Center for Substance Abuse Treatment, *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*; Treatment Improvement Protocol Series 40. - DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004, the drug *Suboxone*® may only be used to treat addictions attributed to Schedule III, IV, or V controlled substances, and not for Schedule II controlled substance addiction. Further, the physician prescribing this drug to treat addiction must be certified to prescribe this drug.

162. **[a]** is the correct answer.

Regarding the sale of dextromethorphan products, the major requirement is that it can only be sold over-the-counter to persons 18 years or older (Calif. Health & Safety Code, Sec. 11110[a][b][c]). The law does not set any restrictions on where and how much can be sold, nor that the purchaser must sign a log book.

163. **[e]** is the correct answer.

If a new prescription is mailed or delivered to the patient's home, the pharmacy is not required to give an oral consultation; but instead, must provide the patient with written notice of his or her right to request consultation, and a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's medication records. (See Title 16, Calif. Code of Regs., Sec. 1707.2[a][3].

164. **[c]** is the correct answer.

While a controlled substance inventory must be taken at least every two years, California requires that the inventory record be kept for 3 years (Calif. Bus. & Prof. Code, Sec. 4333[a]). Even though federal law states that the controlled substance inventory record must be kept for 2 years (Title 21, Code of Fed. Regs., Sec. 1304.04[a]), California law is to be followed in keeping the inventory record for at least 3 years.

165. **[b]** is the correct answer.

In accordance with the Ryan-Haight Online Pharmacy Consumer Act of 2008 any person who plans to operate an “online pharmacy” must obtain DEA registration allowing the pharmacy to be identified as an online pharmacy. An “online pharmacy” is considered one that does its exclusive prescription filling business online, or at least a major part of its business online. (21 USC 829[e][2][C] and 21 Code of Fed. Regs., Sec. 1300.04[b]).

166. **[C]** is the most correct answer.

A pharmacist may furnish a prescription pursuant to a written or oral order from a prescriber licensed in a State other than California. (Title 16, Calif. Code of Regs., Sec. 1717[d]). This includes controlled substance prescriptions. (Calif. Health & Safety Code, Sec. 11164.1)

167. **[a]** is the correct answer.

Calif. Bus. & Prof. Code, Sec. 4052[a][2] states that a pharmacist (also includes a pharmacist intern) may transmit a valid prescription to another pharmacist. Therefore in the transferring of a patient’s prescription to another pharmacy only a pharmacist (or pharmacist intern) can be the only parties that may both transfer and receive this information.

Both pharmacy technicians and clerks are excluded from being allowed to either make or receive these prescription transfers.

168. [d] is the correct answer.

If a prescription for a Schedule III drug is no longer refillable, only the pharmacist or pharmacist intern can contact the prescriber to further continue the prescription. Because the prescription is to be treated like a new prescription, it must be rewritten, and because it is like a new prescription only the pharmacist or pharmacist intern can get the approval from the prescriber's office to continue it. (Calif. Bus. & Prof. Code, Sec. 4070[a]).

169. [e] is the most correct answer.

A pharmacist with an "inactive license may acquire "active" license status by notifying the Board of Pharmacy of the desire to renew their license, and must show proof of satisfying the necessary C.E. requirements mandated by the Board in order to achieve the reinstatement of an "active" license. (Calif. Bus. & Prof. Code, Secs. 701 and 4131[c][d], the September 2010 *Script* (publication of the Calif. State Board of Pharmacy)).

170. [d] is the most correct answer.

A centralized hospital pharmacy in California may do the compounding and preparation of extemporaneous unit dose packaging for any hospital owned by the same owners as the centralized compounding/dose preparation hospital pharmacy. The centralized compounding/dose preparation hospital pharmacy must be located within a 75 mile radius of the other owned hospitals, and the extemporaneous unit doses prepared must have barcoding to be used for the checking of accuracy during the medication administration at the patient's bedside. (Calif. Bus. & Prof. Code, Secs. 4029 and 4128)

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